1395w–21(a)(2)(A) of this title'' in introductory provisions.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114–255 applicable with respect to plan years beginning on or after Jan. 1, 2021, see section 17006(a)(3) of Pub. L. 114–255, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3208(b), Mar. 23, 2010, 124 Stat. 460, provided that: ''The amendment made by this section [amending this section] shall take effect on January 1, 2010, and shall apply to plan years beginning on or after such date.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 164(c)(1), (d)(1), (e)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, and applicable to all specialized Medicare Advantage plans for special needs individuals regardless of when the plan first entered the Medicare Advantage program under this part, see section 164(g) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 221(b)(1), (d)(2) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Amendment by section 231(b), (c) of Pub. L. 108–173 effective Dec. 8, 2003, see section 231(f)(1) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

REGULATIONS

Pub. L. 108–173, title II, § 231(f)(2), Dec. 8, 2003, 117 Stat. 2208, provided that: ''No later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall issue final regulations to establish requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Social Security Act [42 U.S.C. 1395w–28(b)(6)(B)(iii)], as added by subsection (b).''

AUTHORIZATION TO OPERATE; RESOURCES FOR STATE MEDICAID AGENCIES; CONTRACTING REQUIREMENTS

Pub. L. 110–275, title I, § 164(c)(2)–(4), July 15, 2008, 122 Stat. 2573, as amended by Pub. L. 111–148, title III, § 3205(d), Mar. 23, 2010, 124 Stat. 458, provided that:

''(2) AUTHORITY TO OPERATE BUT NO SERVICE AREA EXPANSION FOR DUAL SNPS THAT DO NOT MEET CERTAIN REQUIREMENTS.—Notwithstanding subsection (f) of section 1859 of the Social Security Act (42 U.S.C. 1395w–28), during the period beginning on January 1, 2010, and ending on December 31, 2012, in the case of a specialized Medicare Advantage plan for special needs individuals described in subsection (b)(6)(B)(ii) of such section, as amended by this section, that does not meet the requirement described in subsection (f)(3)(D) of such section, the Secretary of Health and Human Services—

''(A) shall permit such plan to be offered under part C of title XVIII of such Act [42 U.S.C. 1395w–21 et seq.]; and

''(B) shall not permit an expansion of the service area of the plan under such part C.

''(3) RESOURCES FOR STATE MEDICAID AGENCIES.—The Secretary of Health and Human Services shall provide for the designation of appropriate staff and resources that can address State inquiries with respect to the coordination of State and Federal policies for specialized MA plans for special needs individuals described in section 1859(b)(6)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)), as amended by this section.

''(4) NO REQUIREMENT FOR CONTRACT.—Nothing in the provisions of, or amendments made by, this subsection [amending this section] shall require a State to enter into a contract with a Medicare Advantage organization with respect to a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)), as amended by this section.''

PANEL OF CLINICAL ADVISORS TO DETERMINE CONDITIONS

Pub. L. 110–275, title I, § 164(e)(2), July 15, 2008, 122 Stat. 2574, provided that: ''The Secretary of Health and Human Services shall convene a panel of clinical advisors to determine the conditions that meet the definition of severe and disabling chronic conditions under section 1859(b)(6)(B)(iii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(iii)), as amended by paragraph (1). The panel shall include the Director of the Agency for Healthcare Research and Quality (or the Director's designee).''

NO EFFECT ON MEDICAID BENEFITS FOR DUALS

Pub. L. 110–275, title I, § 164(h), July 15, 2008, 122 Stat. 2575, provided that: ''Nothing in the provisions of, or amendments made by, this section [amending this section and sections 1395w–22 and 1395w–27 of this title and enacting provisions set out as notes under this section and sections 1395w–21, 1395w–22, and 1395w–27 of this title] shall affect the benefits available under the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for special needs individuals described in section 1859(b)(6)(B)(ii) of such Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)).''

AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS

Secretary of Health and Human Services authorized, in promulgating regulations to carry out subsection (b)(6) of this section, to provide, notwithstanding subsection (b)(6)(A) of this section, for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals, see section 231(d) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

§ 1395w–29. Repealed. Pub. L. 111–152, title I, § 1102(f), Mar. 30, 2010, 124 Stat. 1046

Section, act Aug. 14, 1935, ch. 531, title XVIII, § 1860C–1, as added Pub. L. 108–173, title II, § 241(a), Dec. 8, 2003, 117 Stat. 2214; amended Pub. L. 111–148, title III, § 3201(a)(2)(D), Mar. 23, 2010, 124 Stat. 444; Pub. L. 111–152, title I, § 1102(a), Mar. 30, 2010, 124 Stat. 1040, related to comparative cost adjustment program.

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

PRIOR PROVISIONS

A prior part D of this subchapter, consisting of section 1395x et seq., was redesignated part E of this subchapter.

SUBPART 1—PART D ELIGIBLE INDIVIDUALS AND PRESCRIPTION DRUG BENEFITS

§ 1395w–101. Eligibility, enrollment, and information

(a) Provision of qualified prescription drug coverage through enrollment in plans

(1) In general

Subject to the succeeding provisions of this part, each part D eligible individual (as de-

fined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1395w–102(a) of this title) as follows:

(A) Fee-for-service enrollees may receive coverage through a prescription drug plan

A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1395w–151(a)(14) of this title).

(B) Medicare Advantage enrollees

(i) Enrollees in a plan providing qualified prescription drug coverage receive coverage through the plan

A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

(ii) Limitation on enrollment of MA plan enrollees in prescription drug plans

Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

(iii) Private fee-for-service enrollees in MA plans not providing qualified prescription drug coverage permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1395w–28(b)(2) of this title) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) Enrollees in MSA plans permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MSA plan (as defined in section 1395w–28(b)(3) of this title) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) Coverage first effective January 1, 2006

Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

(3) Definitions

For purposes of this part:

(A) Part D eligible individual

The term ''part D eligible individual'' means an individual who is entitled to benefits under part A or enrolled under part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under section 1395*o*(b) of this title).

(B) MA plan

The term ''MA plan'' has the meaning given such term in section 1395w–28(b)(1) of this title.

(C) MA–PD plan

The term ''MA–PD plan'' means an MA plan that provides qualified prescription drug coverage.

(b) Enrollment process for prescription drug plans

(1) Establishment of process

(A) In general

The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

(B) Application of MA rules

In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1395w–21 of this title:

(i) Residence requirements

Section 1395w–21(b)(1)(A) of this title, relating to residence requirements.

(ii) Exercise of choice

Section 1395w–21(c) of this title (other than paragraph (3)(A) and paragraph (4) of such section), relating to exercise of choice.

(iii) Coverage election periods

Subject to paragraphs (2) and (3) of this subsection, section 1395w–21(e) of this title (other than subparagraphs (B), (C), (E), and (F) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

(iv) Coverage periods

Section 1395w–21(f) of this title, relating to effectiveness of elections and changes of elections.

(v) Guaranteed issue and renewal

Section 1395w–21(g) of this title (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

(vi) Marketing material and application forms

Section 1395w–21(h) of this title, relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1395w–21(e) of this title shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) Special rule

The process established under subparagraph (A) shall include, except as provided in subparagraph (D), in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title) who has failed to enroll in a prescription drug plan or an

MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1395w–114(a)(1)(A) of this title).[1] If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(D) Special rule for plans that waive de minimis premiums

The process established under subparagraph (A) may include, in the case of a part D eligible individual who is a subsidy eligible individual (as defined in section 1395w–114(a)(3) of this title) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan or MA–PD plan that has waived the monthly beneficiary premium for such subsidy eligible individual under section 1395w–114(a)(5) of this title. If there is more than one such plan available, the Secretary shall enroll such an individual under the preceding sentence on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(2) Initial enrollment period

(A) Program initiation

In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1395w–21(e)(3)(B)(iii) of this title, as applied under paragraph (1)(B)(iii).

(B) Continuing periods

In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1395w–21(e)(1) of this title, as applied under paragraph (1)(B)(iii) of this section,[2] as if ''entitled to benefits under part A or enrolled under part B'' were substituted for ''entitled to benefits under part A and enrolled under part B'', but in no case shall such period end before the period described in subparagraph (A).

(3) Additional special enrollment periods

The Secretary shall establish special enrollment periods, including the following:

(A) Involuntary loss of creditable prescription drug coverage

(i) In general

In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1395w–113(b)(4) of this title).

(ii) Notice

In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) Failure to pay premium

For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) Reduction in coverage

For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1395w–113(b)(5) of this title (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) Errors in enrollment

In the case described in section 1395p(h) of this title (relating to errors in enrollment), in the same manner as such section applies to part B.

(C) Exceptional circumstances

In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) Medicaid coverage

In the case of an individual (as determined by the Secretary, subject to such limits as the Secretary may establish for individuals identified pursuant to section 1395w–104(c)(5) of this title) who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title).

(E) Discontinuance of MA–PD election during first year of eligibility

In the case of a part D eligible individual who discontinues enrollment in an MA–PD plan under the second sentence of section 1395w–21(e)(4) of this title at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

(4) Information to facilitate enrollment

(A) In general

Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

(B) Limitation

(i) Provision of information

The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) Use of information

Such information provided by the Secretary to a PDP sponsor or an MA organi-

[1] So in original. The closing parenthesis probably should not appear.

[2] So in original. Probably should be ''of this subsection,''.

zation may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

(5) Reference to enrollment procedures for MA–PD plans

For rules applicable to enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in MA–PD plans, see section 1395w–21 of this title.

(6) Reference to penalties for late enrollment

Section 1395w–113(b) of this title imposes a late enrollment penalty for part D eligible individuals who—

(A) enroll in a prescription drug plan or an MA–PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) Providing information to beneficiaries

(1) Activities

The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

(2) Requirements

The activities described in paragraph (1) shall—

(A) be similar to the activities performed by the Secretary under section 1395w–21(d) of this title, including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section 1395b–2 of this title.

(3) Comparative information

(A) In general

Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall include a comparison of the following with respect to qualified prescription drug coverage:

(i) Benefits

The benefits provided under the plan.

(ii) Monthly beneficiary premium

The monthly beneficiary premium under the plan.

(iii) Quality and performance

The quality and performance under the plan.

(iv) Beneficiary cost-sharing

The cost-sharing required of part D eligible individuals under the plan.

(v) Consumer satisfaction surveys

The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1395w–104(d) of this title.

(B) Exception for unavailability of information

The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(4) Information on late enrollment penalty

The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1395w–113(b) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–1, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2071; amended Pub. L. 109–432, div. B, title II, §206(b), Dec. 20, 2006, 120 Stat. 2990; Pub. L. 111–148, title III, §3303(b), Mar. 23, 2010, 124 Stat. 469; Pub. L. 114–10, title II, §209(b)(2)(B)(ii), Apr. 16, 2015, 129 Stat. 149; Pub. L. 114–198, title VII, §704(a)(3), July 22, 2016, 130 Stat. 748; Pub. L. 116–260, div. CC, title IV, §402(g), Dec. 27, 2020, 134 Stat. 3002.)

AMENDMENTS

2020—Subsec. (a)(3)(A). Pub. L. 116–260 inserted ''(but not including an individual enrolled solely for coverage of immunosuppressive drugs under section 1395*o*(b) of this title)'' before period at end.

2016—Subsec. (b)(3)(D). Pub. L. 114–198 inserted '', subject to such limits as the Secretary may establish for individuals identified pursuant to section 1395w–104(c)(5) of this title'' after ''the Secretary''.

2015—Subsec. (b)(1)(B)(ii). Pub. L. 114–10, §209(b)(2)(B)(ii)(I), inserted ''and paragraph (4)'' after ''paragraph (3)(A)''.

Subsec. (b)(1)(B)(iii). Pub. L. 114–10, §209(b)(2)(B)(ii)(II), substituted ''(E), and (F)'' for ''and (E)''.

2010—Subsec. (b)(1)(C). Pub. L. 111–148, §3303(b)(1), inserted ''except as provided in subparagraph (D),'' after ''shall include,''.

Subsec. (b)(1)(D). Pub. L. 111–148, §3303(b)(2), added subpar. (D).

2006—Subsec. (b)(1)(B)(iii). Pub. L. 109–432 substituted ''subparagraphs (B), (C), and (E)'' for ''subparagraphs (B) and (C)''.

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title VII, §704(g)(1), July 22, 2016, 130 Stat. 751, provided that: ''The amendments made by this section [amending this section and sections 1395w–104, 1395w–152, 1395ddd, and 1395iii of this title] shall apply to prescription drug plans (and MA–PD plans) for plan years beginning on or after January 1, 2019.''

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3303(c), Mar. 23, 2010, 124 Stat. 469, provided that: ''The amendments made by this subsection [probably should be ''this section'', amending this section and section 1395w–114 of this title] shall apply to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011.''

REGULATIONS

Pub. L. 114–198, title VII, § 704(g)(2), (3), July 22, 2016, 130 Stat. 751, 752, provided that:

''(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

''(A) IN GENERAL.—Not later than January 1, 2017, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.] or enrolled under part B of such title [42 U.S.C. 1395j et seq.], advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B). The input described in the preceding sentence shall be provided to the Secretary in sufficient time in order for the Secretary to take such input into account in promulgating the regulations pursuant to paragraph (3).

''(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

''(i) the anticipated impact of drug management programs for at-risk beneficiaries under paragraph (5) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of such paragraph);

''(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk beneficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act [42 U.S.C. 1395w–21 et seq.] that allow an automatic escalation to external review of claims submitted under such part);

''(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;

''(iv) the manner in which terms and definitions in such paragraph should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph;

''(v) the information to be included in the notices described in subparagraph (B) of such paragraph and the standardization of such notices;

''(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program;

''(vii) notices for plan enrollees at the point of sale that would explain why an at-risk beneficiary has been prohibited from receiving a prescription at a location outside of the designated pharmacy;

''(viii) evidence-based prescribing guidelines for opiates; and

''(ix) the sharing of claims data under parts A and B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] with PDP sponsors.

''(3) RULEMAKING.—Not later than one year after the date of the enactment of this Act [July 22, 2016], the Secretary of Health and Human Services shall, taking into account the input gathered pursuant to paragraph (2)(A) and after providing notice and an opportunity to comment, promulgate regulations to carry out the provisions of, and amendments made by[,] this section [amending this section and sections 1395w–104, 1395w–152, 1395ddd, and 1395iii of this title and enacting provisions set out as a note above].''

OFFICE OF THE INSPECTOR GENERAL STUDIES AND REPORTS

Pub. L. 111–148, title III, § 3313, Mar. 23, 2010, 124 Stat. 477, provided that:

''(a) STUDY AND ANNUAL REPORT ON PART D FORMULARIES' INCLUSION OF DRUGS COMMONLY USED BY DUAL ELIGIBLES.—

''(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA–PD plans under part D [42 U.S.C. 1395w–101 et seq.] include drugs commonly used by full-benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act (42 U.S.C. 1396u–5(c)(6))).

''(2) ANNUAL REPORTS.—Not later than July 1 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

''(b) STUDY AND REPORT ON PRESCRIPTION DRUG PRICES UNDER MEDICARE PART D AND MEDICAID.—

''(1) STUDY.—

''(A) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct a study on prices for covered part D drugs under the Medicare prescription drug program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] and for covered outpatient drugs under title XIX [42 U.S.C. 1396 et seq.]. Such study shall include the following:

''(i) A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title (as determined by the Inspector General based on volume and expenditures), of—

''(I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA–PD plans; and

''(II) the prices paid for covered outpatient drugs by a State plan under title XIX.

''(ii) An assessment of—

''(I) the financial impact of any discrepancies in such prices on the Federal Government; and

''(II) the financial impact of any such discrepancies on enrollees under part D or individuals eligible for medical assistance under a State plan under title XIX.

''(B) PRICE.—For purposes of subparagraph (A), the price of a covered part D drug or a covered outpatient drug shall include any rebate or discount under such program or such title, respectively, including any negotiated price concession described in section 1860D–2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)(B)) or rebate under an agreement under section 1927 of the Social Security Act (42 U.S.C. 1396r–8).

''(C) AUTHORITY TO COLLECT ANY NECESSARY INFORMATION.—Notwithstanding any other provision of law, the Inspector General of the Department of Health and Human Services shall be able to collect any information related to the prices of covered part D drugs under such program and covered outpatient drugs under such title XIX necessary to carry out the comparison under subparagraph (A).

''(2) REPORT.—

''(A) IN GENERAL.—Not later than October 1, 2011, subject to subparagraph (B), the Inspector General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

''(B) LIMITATION ON INFORMATION CONTAINED IN REPORT.—The report submitted under subparagraph (A) shall not include any information that the Inspector General determines is proprietary or is

likely to negatively impact the ability of a PDP sponsor or a State plan under title XIX [42 U.S.C. 1396 et seq.] to negotiate prices for covered part D drugs or covered outpatient drugs, respectively.

''(3) DEFINITIONS.—In this section:

''(A) COVERED PART D DRUG.—The term 'covered part D drug' has the meaning given such term in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)).

''(B) COVERED OUTPATIENT DRUG.—The term 'covered outpatient drug' has the meaning given such term in section 1927(k) of such Act (42 U.S.C. 1396r[–8](k)).

''(C) MA–PD PLAN.—The term 'MA–PD plan' has the meaning given such term in section 1860D–41(a)(9) of such Act (42 U.S.C. 1395w–151(a)(9)).

''(D) MEDICARE ADVANTAGE ORGANIZATION.—The term 'Medicare Advantage organization' has the meaning given such term in section 1859(a)(1) of such Act (42 U.S.C. 1395w–28)[sic](a)(1)).

''(E) PDP SPONSOR.—The term 'PDP sponsor' has the meaning given such term in section 1860D–41(a)(13) of such Act (42 U.S.C. 1395w–151(a)(13)).

''(F) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' has the meaning given such term in section 1860D–41(a)(14) of such Act (42 U.S.C. 1395w–151(a)(14)).''

SUBMISSION OF LEGISLATIVE PROPOSAL

Pub. L. 108–173, title I, §101(b), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than 6 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title and title II [see Tables for classification].''

STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE

Pub. L. 108–173, title I, §101(c), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than January 1, 2005, the Secretary [of Health and Human Services] shall submit a report to Congress that makes recommendations regarding methods for providing benefits under subpart 1 of part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] for outpatient prescription drugs for which benefits are provided under part B of such title [42 U.S.C. 1395j et seq.].''

REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT

Pub. L. 108–173, title I, §101(d), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than March 1, 2005, the Secretary [of Health and Human Services] shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title [see Tables for classification]. The Secretary shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006. The report shall include recommendations regarding an appropriate transition from the program under section 1860D–31 of the Social Security Act [42 U.S.C. 1395w–141] to prescription drug benefits under subpart 1 of part D of title XVIII of such Act [42 U.S.C. 1395w–101 et seq.].''

STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION

Pub. L. 108–173, title I, §106, Dec. 8, 2003, 117 Stat. 2168, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act [Dec. 8, 2003], a State Pharmaceutical Assistance Transition Commission (in this section referred to as the 'Commission') to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.], as added by section 101.

''(2) DEFINITIONS.—For purposes of this section:

''(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term 'State pharmaceutical assistance program' means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act [Dec. 8, 2003] financial assistance to medicare beneficiaries for the purchase of prescription drugs.

''(B) PROGRAM PARTICIPANT.—The term 'program participant' means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

''(b) COMPOSITION.—The Commission shall include the following:

''(1) A representative of each Governor of each State that the Secretary [of Health and Human Services] identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under section 1860D–14 of the Social Security Act [42 U.S.C. 1395w–114].

''(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

''(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

''(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.

''(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify.

The Secretary shall designate a member to serve as Chair of the Commission and the Commission shall meet at the call of the Chair.

''(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

''(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

''(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title [see Tables for classification].

''(3) Principles of medicare modernization under this Act [see Tables for classification].

''(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

''(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

''(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).''

CONFLICT OF INTEREST STUDY

Pub. L. 108–173, title I, §110, Dec. 8, 2003, 117 Stat. 2174, provided that:

''(a) STUDY.—The Federal Trade Commission shall conduct a study of differences in payment amounts for

pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. Such study shall include the following:

''(1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers, and community pharmacies.

''(2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress a report on the study conducted under subsection (a). Such report shall include recommendations regarding any need for legislation to ensure the fiscal integrity of the voluntary prescription drug benefit program under part D of title XVIII [42 U.S.C. 1395w–101 et seq.], as added by section 101, that may be appropriated as the result of such study.

''(c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information under subsection (a).''

§ 1395w–102. Prescription drug benefits

(a) Requirements

(1) In general

For purposes of this part and part C, the term ''qualified prescription drug coverage'' means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices

Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices

Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing

(I) In general

A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) Construction

Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) Optional drugs

Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) Requirement

A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) Basic prescription drug coverage

For purposes of this part and part C, the term ''basic prescription drug coverage'' means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions

The provisions of section 1395w–22(a)(4) of this title shall apply under this part in the same manner as they apply under part C.

(5) Construction

Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) Standard prescription drug coverage

For purposes of this part and part C, the term ''standard prescription drug coverage'' means coverage of covered part D drugs that meets the following requirements:

(1) Deductible

(A) In general

The coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) Benefit structure

(A) 25 percent coinsurance

Subject to subparagraphs (C) and (D), the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of 25 percent of such costs.

(B) Use of tiers

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organi-

zation from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) Coverage for generic drugs in coverage gap

(i) In general

Except as provided in paragraph (4), the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the generic-gap coinsurance percentage (specified in clause (ii)) for the year; or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Generic-gap coinsurance percentage

The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 and each subsequent year is 25 percent.

(D) Coverage for applicable drugs in coverage gap

(i) In general

Except as provided in paragraph (4), the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for the negotiated price (as defined in section 1395w–114a(g)(6) of this title) of covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the difference between—

(aa) the applicable gap percentage (specified in clause (ii) for the year); and

(bb) the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs (or, in the case of a year after 2018, 50 percent); or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Applicable gap percentage

The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent; and

(V) 2019 and each subsequent year is 75 percent.

(3) Initial coverage limit

(A) In general

Except as provided in paragraphs (2)(C), (2)(D), and (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(4) Protection against high out-of-pocket expenditures

(A) In general

(i) In general

The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of—

(I) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396r–8(k)(7)(A)(i) of this title) and $5 for any other drug; or

(II) coinsurance that is equal to 5 percent.

(ii) Adjustment of amount

For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents.

(B) Annual out-of-pocket threshold

(i) In general

For purposes of this part, the ''annual out-of-pocket threshold'' specified in this subparagraph—

(I) for 2006, is equal to $3,600;

(II) for each of years 2007 through 2013, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage in-

crease described in paragraph (6) for the year involved;

(III) for 2014 and 2015, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved, minus 0.25 percentage point;

(IV) for each of years 2016 through 2019, is equal to the amount specified in this subparagraph for the previous year, increased by the lesser of—

(aa) the annual percentage increase described in paragraph (7) for the year involved, plus 2 percentage points; or

(bb) the annual percentage increase described in paragraph (6) for the year;

(V) for 2020, is equal to the amount that would have been applied under this subparagraph for 2020 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 had not been enacted; or

(VI) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) Rounding

Any amount determined under clause (i)(II) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) Application

Except as provided in subparagraph (E), in applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary;

(ii) subject to clause (iii), such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual) and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs; and

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs are borne or paid—

(I) under section 1395w–114 of this title;

(II) under a State Pharmaceutical Assistance Program;

(III) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 1603 of title 25); or

(IV) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act [42 U.S.C. 300ff–21 et seq.].

(D) Information regarding third-party reimbursement

(i) Procedures for exchanging information

In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) Authority to request information from enrollees

A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1395w–21(g)(3)(B) of this title (and as applied under this part under section 1395w–101(b)(1)(B)(v) of this title) for a period specified by the Secretary.

(E) Inclusion of costs of applicable drugs under medicare coverage gap discount program

In applying subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1395w–114a(g) of this title) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(5) Construction

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) Annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(7) Additional annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(c) Alternative prescription drug coverage requirements

A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1395w–111(c) of this title) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) Assuring at least actuarially equivalent coverage

(A) Assuring equivalent value of total coverage

The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) Assuring equivalent unsubsidized value of coverage

The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1395w–115 of this title with respect to such coverage.

(C) Assuring standard payment for costs at initial coverage limit

The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year exceeds the deductible described in subsection (b)(1) for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

(2) Maximum required deductible

The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

(3) Same protection against high out-of-pocket expenditures

The coverage provides the coverage required under subsection (b)(4).

(d) Access to negotiated prices

(1) Access

(A) In general

Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3)).

(B) Negotiated prices

For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) Medicaid-related provisions

The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396r–8(c)(1)(C) of this title.

(2) Disclosure

A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed to the Secretary under this paragraph.

(3) Audits

To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) Covered part D drug defined

(1) In general

Except as provided in this subsection, for purposes of this part, the term ''covered part D drug'' means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title; or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) Exclusions

(A) In general

Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1396r–8(d)(2) of this title, other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1396r–8(d)(3) of this title, as such sections were in effect on December 8, 2003. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) Medicare covered drugs

A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

(3) Application of general exclusion provisions

A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1395y(a) of this title applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1395w–104 of this title.

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term ''medically accepted indication'' has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

(I) ''prescription drug plan or MA–PD plan'' shall be substituted for ''carrier'' each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r–8(k)(6) of this title.

(B) Conflict of interest

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title meets[1] the requirement in the third sentence of section 1395x(t)(2)(B) of this title.

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1396r–8(g)(1)(B)(i) of this title as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1395x(t)(2)(B) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–2, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2075; amended Pub. L. 109–91, title I, § 103(a), Oct. 20, 2005, 119 Stat. 2092; Pub. L. 109–432, div. B, title II, § 202(b), Dec. 20, 2006, 120 Stat. 2986; Pub. L. 110–275, title I, §§ 175(a), 182(a)(1), July 15, 2008, 122 Stat. 2581, 2583; Pub. L. 111–148, title III, §§ 3301(c)(1), 3314(a), 3315, Mar. 23, 2010, 124 Stat. 467, 478, 479; Pub. L. 111–152, title I, § 1101(a)(2), (b)(3), (d), Mar. 30, 2010, 124 Stat. 1037–1039; Pub. L. 115–123, div. E, title XII, § 53116(a), Feb. 9, 2018, 132 Stat. 306.)

REFERENCES IN TEXT

Section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010, referred to in subsec. (b)(4)(B)(i)(V), is section 1101(d)(1) of Pub. L. 111–152, which amended this section.

The Public Health Service Act, referred to in subsec. (b)(4)(C)(iii)(IV), is act July 1, 1944, ch. 373, 58 Stat. 682. Part B of title XXVI of the Act is classified generally to part B (§ 300ff–21 et seq.) of subchapter XXIV of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

AMENDMENTS

2018—Subsec. (b)(2)(D)(i)(I). Pub. L. 115–123, § 53116(a)(1), amended subcl. (I) generally. Prior to

[1] So in original. Probably should be ''meet''.

amendment, subcl. (I) read as follows: ''equal to the difference between the applicable gap percentage (specified in clause (ii) for the year) and the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs; or''.

Subsec. (b)(2)(D)(ii)(V), (VI). Pub. L. 115–123, § 53116(a)(2), substituted ''2019'' for ''2020'' in subcl. (VI), redesignated subcl. (VI) as (V), and struck out former subcl. (V) which read as follows: ''2019 is 80 percent; and''.

2010—Subsec. (b)(2)(A). Pub. L. 111–152, § 1101(b)(3)(A), substituted ''Subject to subparagraphs (C) and (D), the coverage'' for ''The coverage''.

Subsec. (b)(2)(B). Pub. L. 111–152, § 1101(b)(3)(B), substituted ''subparagraphs (A)(ii), (C), and (D)'' for ''subparagraph (A)(ii)''.

Subsec. (b)(2)(C), (D). Pub. L. 111–152, § 1101(b)(3)(C), added subpars. (C) and (D).

Subsec. (b)(3)(A). Pub. L. 111–152, § 1101(b)(3)(D), substituted ''paragraphs (2)(C), (2)(D), and (4)'' for ''paragraph (4)''.

Pub. L. 111–148, § 3315(1), which directed substitution of ''paragraphs (4) and (7)'' for ''paragraph (4)'' in introductory provisions, was repealed by Pub. L. 111–152, § 1101(a)(2). See Construction of 2010 Amendment note below.

Subsec. (b)(4)(B)(i)(II) to (VI). Pub. L. 111–152, § 1101(d)(1), added subcls. (II) to (V) and redesignated former subcl. (II) as (VI).

Subsec. (b)(4)(C). Pub. L. 111–148, § 3314(a), in cl. (ii), substituted ''subject to clause (iii), such costs shall be treated as incurred only if'' for ''such costs shall be treated as incurred only if'' and struck out '', under section 1395w–114 of this title, or under a State Pharmaceutical Assistance Program'' after ''on behalf of the individual),'', and added cl. (iii).

Pub. L. 111–148, § 3301(c)(1)(A), substituted ''Except as provided in subparagraph (E), in applying'' for ''In applying'' in introductory provisions.

Subsec. (b)(4)(E). Pub. L. 111–152, § 1101(b)(3)(E), inserted before period at end '', except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D)''.

Pub. L. 111–148, § 3301(c)(1)(B), added subpar. (E).

Subsec. (b)(7). Pub. L. 111–152, § 1101(d)(2), added par. (7).

Pub. L. 111–148, § 3315(2), which directed addition of par. (7), was repealed by Pub. L. 111–152, § 1101(a)(2). As enacted, text read as follows:

''(A) IN GENERAL.—For the plan year beginning on January 1, 2010, the initial coverage limit described in paragraph (3)(B) otherwise applicable shall be increased by $500.

''(B) APPLICATION.—In applying subparagraph (A)—

''(i) except as otherwise provided in this subparagraph, there shall be no change in the premiums, bids, or any other parameters under this part or part C;

''(ii) costs that would be treated as incurred costs for purposes of applying paragraph (4) but for the application of subparagraph (A) shall continue to be treated as incurred costs;

''(iii) the Secretary shall establish procedures, which may include a reconciliation process, to fully reimburse PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans for the reduction in beneficiary cost sharing associated with the application of subparagraph (A);

''(iv) the Secretary shall develop an estimate of the additional increased costs attributable to the application of this paragraph for increased drug utilization and financing and administrative costs and shall use such estimate to adjust payments to PDP sponsors with respect to prescription drug plans under this part and MA organizations with respect to MA–PD plans under part C; and

''(v) the Secretary shall establish procedures for retroactive reimbursement of part D eligible individuals who are covered under such a plan for costs which are incurred before the date of initial implementation of subparagraph (A) and which would be reimbursed under such a plan if such implementation occurred as of January 1, 2010.

''(C) NO EFFECT ON SUBSEQUENT YEARS.—The increase under subparagraph (A) shall only apply with respect to the plan year beginning on January 1, 2010, and the initial coverage limit for plan years beginning on or after January 1, 2011, shall be determined as if subparagraph (A) had never applied.''

See Construction of 2010 Amendment note below.

2008—Subsec. (e)(1). Pub. L. 110–275, § 182(a)(1)(A), substituted ''(as defined in paragraph (4))'' for ''(as defined in section 1396r–8(k)(6) of this title)'' in concluding provisions.

Subsec. (e)(2)(A). Pub. L. 110–275, § 175(a), inserted ''other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines),'' after ''agents),''.

Subsec. (e)(4). Pub. L. 110–275, § 182(a)(1)(B), which directed amendment of subsec. (e)(1) in the matter following subpar. (B) by adding par. (4) at the end, was executed by adding par. (4) at end of subsec. (e), to reflect the probable intent of Congress.

2006—Subsec. (e)(1). Pub. L. 109–432 inserted ''(and, for vaccines administered on or after January 1, 2008, its administration)'' after ''section 262 of this title'' in concluding provisions.

2005—Subsec. (e)(2)(A). Pub. L. 109–91, § 103(a)(2), inserted at end ''Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.''

Pub. L. 109–91, § 103(a)(1), inserted before period at end '', as such sections were in effect on December 8, 2003''.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3301(c)(2), Mar. 23, 2010, 124 Stat. 468, provided that: ''The amendments made by this subsection [amending this section] shall apply to costs incurred on or after July 1, 2010.''

Pub. L. 111–148, title III, § 3314(b), Mar. 23, 2010, 124 Stat. 479, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to costs incurred on or after January 1, 2011.''

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, § 175(b), July 15, 2008, 122 Stat. 2581, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to prescriptions dispensed on or after January 1, 2013.''

Pub. L. 110–275, title I, § 182(a)(2), July 15, 2008, 122 Stat. 2583, provided that: ''The amendments made by this subsection [amending this section] shall apply to plan years beginning on or after January 1, 2009.''

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–91, title I, § 103(c), Oct. 20, 2005, 119 Stat. 2092, provided that: ''The amendment made by subsection (a)(1) [amending this section] shall take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) and the amendment made by subsection (a)(2) [amending this section] shall apply to coverage for drugs dispensed on or after January 1, 2007.''

CONSTRUCTION OF 2010 AMENDMENT

Pub. L. 111–152, title I, § 1101(a)(2), Mar. 30, 2010, 124 Stat. 1037, provided that: ''Section 3315 of the Patient Protection and Affordable Care Act [section 3315 of Pub. L. 111–148, amending this section] (including the amendments made by such section) is repealed, and any provision of law amended or repealed by such sections

[sic] is hereby restored or revived as if such section had not been enacted into law.''

CONSTRUCTION

Pub. L. 109–91, title I, §103(b), Oct. 20, 2005, 119 Stat. 2092, provided that: ''Nothing in this section [amending this section and enacting provisions set out as a note under this section] shall be construed as preventing a prescription drug plan or an MA–PD plan from providing coverage of drugs for the treatment of sexual or erectile dysfunction as supplemental prescription drug coverage under section 1860D–2(a)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–102(a)(2)(A)(ii)).''

PAYMENT FOR ADMINISTRATION OF PART D VACCINES IN 2007

Pub. L. 109–432, div. B, title II, §202(a), Dec. 20, 2006, 120 Stat. 2986, provided that: ''Notwithstanding any other provision of law, in the case of a vaccine that is a covered part D drug under section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) and that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B) [probably should be 1395x(s)(10)(B)]).''

§ 1395w–103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage

(1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) Qualifying plan defined

For purposes of this section, the term ''qualifying plan'' means—

(A) a prescription drug plan; or

(B) an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title.

(b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) in an area—

(1) the Secretary may approve limited risk plans under section 1395w–111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w–111(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–3, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2081.)

§ 1395w–104. Beneficiary protections for qualified prescription drug coverage

(a) Dissemination of information

(1) General information

(A) Application of MA information

A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1395w–22(c)(1) of this title relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and, subject to subparagraph (C), including the information described in subparagraph (B).

(B) Drug specific information

The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

(I) the risks associated with prolonged opioid use; and

(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

(aa) in the case of an MA–PD plan under part C, under such plan; and

(bb) in the case of a prescription drug plan, under such plan and under parts A and B.

(C) Targeted provision of information

A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each en-

rollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(2) Disclosure upon request of general coverage, utilization, and grievance information

Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1395w–22(c)(2) of this title to such individual.

(3) Provision of specific information

(A) Response to beneficiary questions

Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the Internet

A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information

A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1395b–7(a) of this title or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1395w–102(b)(4)(C) of this title to the extent practicable, as specified by the Secretary.

(b) Access to covered part D drugs

(1) Assuring pharmacy access

(A) Participation of any willing pharmacy

A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies

For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1395w–115 of this title to a plan.

(C) Convenient access for network pharmacies

(i) In general

The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) Application of TRICARE standards

The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) Adequate emergency access

Such rules shall include adequate emergency access for enrollees.

(iv) Convenient access in long-term care facilities

Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25).

(D) Level playing field

Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

(E) Not required to accept insurance risk

The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) Use of standardized technology

(A) In general

The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1395w–102(d) of this title.

(B) Standards

(i) In general

The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such

standards shall be compatible with part C of subchapter XI and may be based on standards developed by an appropriate standard setting organization.

(ii) Consultation

In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) Implementation

The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) Requirements on development and application of formularies

If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) Development and revision by a pharmacy and therapeutic (P&T) committee

(i) In general

The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) Inclusion of independent experts

Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

(I) is independent and free of conflict with respect to the sponsor and plan; and

(II) has expertise in the care of elderly or disabled persons.

(B) Formulary development

In developing and reviewing the formulary, the committee shall—

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) Inclusion of drugs in all therapeutic categories and classes

(i) In general

Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) Model guidelines

The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) Limitation on changes in therapeutic classification

The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) Provider and patient education

The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) Notice before removing drug from formulary or changing preferred or tier status of drug

Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

(F) Periodic evaluation of protocols

In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) Required inclusion of drugs in certain categories and classes

(i) Formulary requirements

(I) In general

Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) Exceptions

The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) Identification of drugs in certain categories and classes

(I) In general

Subject to clause (iv), the Secretary shall identify, as appropriate, categories

and classes of drugs for which the Secretary determines are of clinical concern.

(II) Criteria

The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) Implementation

The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) Requirement for certain categories and classes until criteria established

Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.
(II) Antidepressants.
(III) Antineoplastics.
(IV) Antipsychotics.
(V) Antiretrovirals.
(VI) Immunosuppressants for the treatment of transplant rejection.

(H) Use of single, uniform exceptions and appeals process

Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(4) Ensuring access during COVID–19 public health emergency period

(A) In general

During the emergency period described in section 1320b–5(g)(1)(B) of this title, subject to subparagraph (B), a prescription drug plan or MA–PD plan shall, notwithstanding any cost and utilization management, medication therapy management, or other such programs under this part, permit a part D eligible individual enrolled in such plan to obtain in a single fill or refill, at the option of such individual, the total day supply (not to exceed a 90-day supply) prescribed for such individual for a covered part D drug.

(B) Safety edit exception

A prescription drug plan or MA–PD plan may not permit a part D eligible individual to obtain a single fill or refill inconsistent with an applicable safety edit.

(c) Cost and utilization management; quality assurance; medication therapy management program

(1) In general

The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1396r–8(k)(7)(A)(i) of this title).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

(E) A utilization management tool to prevent drug abuse (as described in paragraph (6)(A)).[1]

(F) With respect to plan years beginning on or after January 1, 2022, a drug management program for at-risk beneficiaries described in paragraph (5).

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) Medication therapy management program

(A) Description

(i) In general

A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) Targeted beneficiaries described

Targeted beneficiaries described in this clause are the following:

(I) Part D eligible individuals who—

(aa) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(bb) are taking multiple covered part D drugs; and

(cc) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).

(B) Elements

Such program—

(i) may include elements that promote—

(I) enhanced enrollee understanding to promote the appropriate use of medica-

[1] So in original. Probably means first par. (6).

tions by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(II) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(III) detection of adverse drug events and patterns of overuse and underuse of prescription drugs; and

(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—

(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under section 1395w–22(n)(2) of this title, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and

(II) cost-effective means by which an enrollee may so safely dispose of such drugs.

(C) Required interventions

For plan years beginning on or after the date that is 2 years after March 23, 2010, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) Assessment

The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E)[2] Automatic enrollment with ability to opt-out

The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E)[2] Development of program in cooperation with licensed pharmacists

Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) Coordination with care management plans

The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1395b–8 of this title.

(G) Considerations in pharmacy fees

The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed under this subparagraph.

(3) Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities

The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

[2] So in original. Two subpars. (E) have been enacted.

(4) Requiring valid prescriber National Provider Identifiers on pharmacy claims

(A) In general

For plan year 2016 and subsequent plan years, the Secretary shall require a claim for a covered part D drug for a part D eligible individual enrolled in a prescription drug plan under this part or an MA–PD plan under part C to include a prescriber National Provider Identifier that is determined to be valid under the procedures established under subparagraph (B)(i).

(B) Procedures

(i) Validity of prescriber National Provider Identifiers

The Secretary, in consultation with appropriate stakeholders, shall establish procedures for determining the validity of prescriber National Provider Identifiers under subparagraph (A).

(ii) Informing beneficiaries of reason for denial

The Secretary shall establish procedures to ensure that, in the case that a claim for a covered part D drug of an individual described in subparagraph (A) is denied because the claim does not meet the requirements of this paragraph, the individual is properly informed at the point of service of the reason for the denial.

(C) Report

Not later than January 1, 2018, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the effectiveness of the procedures established under subparagraph (B)(i).

(D) Notification and additional requirements with respect to outlier prescribers of opioids

(i) Notification

Not later than January 1, 2021, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information as specified in accordance with clause (iii).

(ii) Identification of outlier prescribers of opioids

(I) In general

The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA–PD plans under part C and based on the thresholds established under subclause (II), identify prescribers that are outlier opioids prescribers for a period of time specified by the Secretary.

(II) Establishment of thresholds

For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish thresholds, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.

(III) Exclusions

The following shall not be included in the analysis for identifying outlier prescribers of opioids under this clause:

(aa) Claims for covered part D drugs for part D eligible individuals who are receiving hospice care under this subchapter.

(bb) Claims for covered part D drugs for part D eligible individuals who are receiving oncology services under this subchapter.

(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Inspector General of the Department of Health and Human Services.

(iii) Contents of notification

The Secretary shall include the following information in the notifications provided under clause (i):

(I) Information on how such prescriber compares to other prescribers within the same specialty and geographic area.

(II) Information on opioid prescribing guidelines, based on input from stakeholders, that may include the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain and guidelines developed by physician organizations.

(III) Other information determined appropriate by the Secretary.

(iv) Modifications and expansions

(I) Frequency

Beginning 5 years after October 24, 2018, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input and changes in opioid prescribing utilization and trends.

(II) Expansion to other prescriptions

The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.

(v) Additional requirements for persistent outlier prescribers

In the case of a prescriber who the Secretary determines is persistently identified under clause (ii) as an outlier prescriber of opioids, the following shall apply:

(I) Such prescriber may be required to enroll in the program under this sub-

chapter under section 1395cc(j) of this title if such prescriber is not otherwise required to enroll, but only after other appropriate remedies have been provided, such as the provision of education funded through section 6052 of the SUPPORT for Patients and Communities Act, for a period determined by the Secretary as sufficient to correct the prescribing patterns that lead to identification of such prescriber as a persistent outlier prescriber of opioids. The Secretary shall determine the length of the period for which such prescriber is required to maintain such enrollment, which shall be the minimum period necessary to correct such prescribing patterns.

(II) Not less frequently than annually (and in a form and manner determined appropriate by the Secretary), the Secretary, consistent with clause(iv)(I), shall communicate information on such prescribers to sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan.

(vi) Public availability of information

The Secretary shall make aggregate information under this subparagraph available on the internet website of the Centers for Medicare & Medicaid Services. Such information shall be in a form and manner determined appropriate by the Secretary and shall not identify any specific prescriber. In carrying out this clause, the Secretary shall consult with interested stakeholders.

(vii) Opioids defined

For purposes of this subparagraph, the term ''opioids'' has such meaning as specified by the Secretary.

(viii) Other activities

Nothing in this subparagraph shall preclude the Secretary from conducting activities that provide prescribers with information as to how they compare to other prescribers that are in addition to the activities under this subparagraph, including activities that were being conducted as October 24, 2018.

(5) Drug management program for at-risk beneficiaries

(A) Authority to establish

A PDP sponsor may (and for plan years beginning on or after January 1, 2022, a PDP sponsor shall) establish a drug management program for at-risk beneficiaries under which, subject to subparagraph (B), the PDP sponsor may, in the case of an at-risk beneficiary for prescription drug abuse who is an enrollee in a prescription drug plan of such PDP sponsor, limit such beneficiary's access to coverage for frequently abused drugs under such plan to frequently abused drugs that are prescribed for such beneficiary by one or more prescribers selected under subparagraph (D), and dispensed for such beneficiary by one or more pharmacies selected under such subparagraph.

(B) Requirement for notices

(i) In general

A PDP sponsor may not limit the access of an at-risk beneficiary for prescription drug abuse to coverage for frequently abused drugs under a prescription drug plan until such sponsor—

(I) provides to the beneficiary an initial notice described in clause (ii) and a second notice described in clause (iii); and

(II) verifies with the providers of the beneficiary that the beneficiary is an at-risk beneficiary for prescription drug abuse.

(ii) Initial notice

An initial notice described in this clause is a notice that provides to the beneficiary—

(I) notice that the PDP sponsor has identified the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse;

(II) information describing all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services;

(III) notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(IV) a request for the beneficiary to submit to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor to select under subparagraph (D) in the case that the beneficiary is identified as an at-risk beneficiary for prescription drug abuse as described in clause (iii)(I);

(V) an explanation of the meaning and consequences of the identification of the beneficiary as potentially being an at-risk beneficiary for prescription drug abuse, including an explanation of the drug management program established by the PDP sponsor pursuant to subparagraph (A);

(VI) clear instructions that explain how the beneficiary can contact the PDP sponsor in order to submit to the PDP sponsor the preferences described in subclause (IV) and any other communications relating to the drug management program for at-risk beneficiaries established by the PDP sponsor; and

(VII) contact information for other organizations that can provide the beneficiary with assistance regarding such drug management program (similar to the information provided by the Secretary in other standardized notices provided to part D eligible individuals en-

rolled in prescription drug plans under this part).

(iii) Second notice

A second notice described in this clause is a notice that provides to the beneficiary notice—

(I) that the PDP sponsor has identified the beneficiary as an at-risk beneficiary for prescription drug abuse;

(II) that such beneficiary is subject to the requirements of the drug management program for at-risk beneficiaries established by such PDP sponsor for such plan;

(III) of the prescriber (or prescribers) and pharmacy (or pharmacies) selected for such individual under subparagraph (D);

(IV) of, and information about, the beneficiary's right to appeal such identification under subsection (h), including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution;

(V) that the beneficiary can, in the case that the beneficiary has not previously submitted to the PDP sponsor preferences for which prescribers and pharmacies the beneficiary would prefer the PDP sponsor select under subparagraph (D), submit such preferences to the PDP sponsor; and

(VI) that includes clear instructions that explain how the beneficiary can contact the PDP sponsor.

(iv) Timing of notices

(I) In general

Subject to subclause (II), a second notice described in clause (iii) shall be provided to the beneficiary on a date that is not less than 30 days after an initial notice described in clause (ii) is provided to the beneficiary.

(II) Exception

In the case that the PDP sponsor, in conjunction with the Secretary, determines that concerns identified through rulemaking by the Secretary regarding the health or safety of the beneficiary or regarding significant drug diversion activities require the PDP sponsor to provide a second notice described in clause (iii) to the beneficiary on a date that is earlier than the date described in subclause (I), the PDP sponsor may provide such second notice on such earlier date.

(C) At-risk beneficiary for prescription drug abuse

(i) In general

Except as provided in clause (v), for purposes of this paragraph, the term ''at-risk beneficiary for prescription drug abuse'' means a part D eligible individual who is not an exempted individual described in clause (ii) and—

(I) who is identified as such an at-risk beneficiary through the use of clinical guidelines that indicate misuse or abuse of prescription drugs described in subparagraph (G) and that are developed by the Secretary in consultation with PDP sponsors and other stakeholders, including individuals entitled to benefits under part A or enrolled under part B, advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers; or

(II) with respect to whom the PDP sponsor of a prescription drug plan, upon enrolling such individual in such plan, received notice from the Secretary that such individual was identified under this paragraph to be an at-risk beneficiary for prescription drug abuse under the prescription drug plan in which such individual was most recently previously enrolled and such identification has not been terminated under subparagraph (F).

(ii) Exempted individual described

An exempted individual described in this clause is an individual who—

(I) receives hospice care under this subchapter;

(II) is a resident of a long-term care facility, of a facility described in section 1396d(d) of this title, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

(III) the Secretary elects to treat as an exempted individual for purposes of clause (i).

(iii) Program size

The Secretary shall establish policies, including the guidelines developed under clause (i)(I) and the exemptions under clause (ii)(III), to ensure that the population of enrollees in a drug management program for at-risk beneficiaries operated by a prescription drug plan can be effectively managed by such plans.

(iv) Clinical contact

With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by a PDP sponsor, the PDP sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions.

(v) Treatment of enrollees with a history of opioid-related overdose

(I) In general

For plan years beginning not later than January 1, 2021, a part D eligible individual who is not an exempted individual described in clause (ii) and who is identified under this clause as a part D eligible individual with a history of

opioid-related overdose (as defined by the Secretary) shall be included as a potentially at-risk beneficiary for prescription drug abuse under the drug management program under this paragraph.

(II) Identification and notice

For purposes of this clause, the Secretary shall—

(aa) identify part D eligible individuals with a history of opioid-related overdose (as so defined); and

(bb) notify the PDP sponsor of the prescription drug plan in which such an individual is enrolled of such identification.

(D) Selection of prescribers and pharmacies

(i) In general

With respect to each at-risk beneficiary for prescription drug abuse enrolled in a prescription drug plan offered by such sponsor, a PDP sponsor shall, based on the preferences submitted to the PDP sponsor by the beneficiary pursuant to clauses (ii)(IV) and (iii)(V) of subparagraph (B) (except as otherwise provided in this subparagraph) select—

(I) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, individual who is authorized to prescribe frequently abused drugs (referred to in this paragraph as a ''prescriber'') who may write prescriptions for such drugs for such beneficiary; and

(II) one, or, if the PDP sponsor reasonably determines it necessary to provide the beneficiary with reasonable access under clause (ii), more than one, pharmacy that may dispense such drugs to such beneficiary.

For purposes of subclause (II), in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

(ii) Reasonable access

In making the selections under this subparagraph—

(I) a PDP sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs (as defined in subparagraph (G)), taking into account geographic location, beneficiary preference, impact on costsharing, and reasonable travel time; and

(II) a PDP sponsor shall ensure such access (including access to prescribers and pharmacies with respect to frequently abused drugs) in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

(iii) Beneficiary preferences

If an at-risk beneficiary for prescription drug abuse submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select in response to a notice under subparagraph (B), the PDP sponsor shall—

(I) review such preferences;

(II) select or change the selection of prescribers and pharmacies for the beneficiary based on such preferences; and

(III) inform the beneficiary of such selection or change of selection.

(iv) Exception regarding beneficiary preferences

In the case that the PDP sponsor determines that a change to the selection of prescriber or pharmacy under clause (iii)(II) by the PDP sponsor is contributing or would contribute to prescription drug abuse or drug diversion by the beneficiary, the PDP sponsor may change the selection of prescriber or pharmacy for the beneficiary without regard to the preferences of the beneficiary described in clause (iii). If the PDP sponsor changes the selection pursuant to the preceding sentence, the PDP sponsor shall provide the beneficiary with—

(I) at least 30 days written notice of the change of selection; and

(II) a rationale for the change.

(v) Confirmation

Before selecting a prescriber or pharmacy under this subparagraph, a PDP sponsor must notify the prescriber and pharmacy that the beneficiary involved has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber and pharmacy has been selected as the beneficiary's designated prescriber and pharmacy.

(E) Terminations and appeals

The identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph, a coverage determination made under a drug management program for at-risk beneficiaries, the selection of prescriber or pharmacy under subparagraph (D), and information to be shared under subparagraph (I), with respect to such individual, shall be subject to reconsideration and appeal under subsection (h) and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.

(F) Termination of identification

(i) In general

The Secretary shall develop standards for the termination of identification of an individual as an at-risk beneficiary for prescription drug abuse under this paragraph. Under such standards such identification shall terminate as of the earlier of—

(I) the date the individual demonstrates that the individual is no longer likely, in the absence of the restrictions under this paragraph, to be an at-risk

beneficiary for prescription drug abuse described in subparagraph (C)(i); and

(II) the end of such maximum period of identification as the Secretary may specify.

(ii) Rule of construction

Nothing in clause (i) shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary for prescription drug abuse under subparagraph (C)(i) after such termination on the basis of additional information on drug use occurring after the date of notice of such termination.

(G) Frequently abused drug

For purposes of this subsection, the term ''frequently abused drug'' means a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted.

(H) Data disclosure

(i) Data on decision to impose limitation

In the case of an at-risk beneficiary for prescription drug abuse (or an individual who is a potentially at-risk beneficiary for prescription drug abuse) whose access to coverage for frequently abused drugs under a prescription drug plan has been limited by a PDP sponsor under this paragraph, the Secretary shall establish rules and procedures to require the PDP sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

(ii) Data to reduce fraud, abuse, and waste

The Secretary shall establish rules and procedures to require PDP sponsors operating a drug management program for at-risk beneficiaries under this paragraph to provide the Secretary with such data as the Secretary determines appropriate for purposes of identifying patterns of prescription drug utilization for plan enrollees that are outside normal patterns and that may indicate fraudulent, medically unnecessary, or unsafe use.

(I) Sharing of information for subsequent plan enrollments

The Secretary shall establish procedures under which PDP sponsors who offer prescription drug plans shall share information with respect to individuals who are at-risk beneficiaries for prescription drug abuse (or individuals who are potentially at-risk beneficiaries for prescription drug abuse) and enrolled in a prescription drug plan and who subsequently disenroll from such plan and enroll in another prescription drug plan offered by another PDP sponsor.

(J) Privacy issues

Prior to the implementation of the rules and procedures under this paragraph, the Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subparagraphs (H) and (I) by PDP sponsors. Such clarification shall provide that the sharing of such data shall be considered to be protected health information in accordance with the requirements of the regulations promulgated pursuant to such section 264(c).

(K) Education

The Secretary shall provide education to enrollees in prescription drug plans of PDP sponsors and providers regarding the drug management program for at-risk beneficiaries described in this paragraph, including education—

(i) provided by Medicare administrative contractors through the improper payment outreach and education program described in section 1395kk–1(h) of this title; and

(ii) through current education efforts (such as State health insurance assistance programs described in subsection (a)(1)(A) of section 119 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395b–3 note)) and materials directed toward such enrollees.

(L) Application under MA–PD plans

Pursuant to section 1395w–131(c)(1) of this title, the provisions of this paragraph apply under part D to MA organizations offering MA–PD plans to MA eligible individuals in the same manner as such provisions apply under this part to a PDP sponsor offering a prescription drug plan to a part D eligible individual.

(M) CMS compliance review

The Secretary shall ensure that existing plan sponsor compliance reviews and audit processes include the drug management programs for at-risk beneficiaries under this paragraph, including appeals processes under such programs.

(6)[3] Utilization management tool to prevent drug abuse

(A) In general

A tool described in this paragraph is any of the following:

(i) A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies.

(ii) Retrospective utilization review to identify—

(I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and

(II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries.

(iii) Consultation with the contractor described in subparagraph (B) to verify if an

[3] So in original. Two pars. (6) have been enacted.

individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I).

(B) Reporting

A PDP sponsor offering a prescription drug plan (and an MA organization offering an MA–PD plan) in a State shall submit to the Secretary and the Medicare drug integrity contractor with which the Secretary has entered into a contract under section 1395ddd of this title with respect to such State a report, on a monthly basis, containing information on—

(i) any provider of services or supplier described in subparagraph (A)(ii)(II) that is identified by such plan sponsor (or organization) during the 30-day period before such report is submitted; and

(ii) the name and prescription records of individuals described in paragraph (5)(C).

(C) CMS compliance review

The Secretary shall ensure that plan sponsor compliance reviews and program audits biennially include a certification that utilization management tools under this paragraph are in compliance with the requirements for such tools.

(6)[3] Providing prescription drug plans with parts A and B claims data to promote the appropriate use of medications and improve health outcomes

(A) Process

Subject to subparagraph (B), the Secretary shall establish a process under which a PDP sponsor of a prescription drug plan may submit a request for the Secretary to provide the sponsor, on a periodic basis and in an electronic format, beginning in plan year 2020, data described in subparagraph (D) with respect to enrollees in such plan. Such data shall be provided without regard to whether such enrollees are described in clause (ii) of paragraph (2)(A).

(B) Purposes

A PDP sponsor may use the data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in clause (i) of paragraph (2)(A).

(ii) To improving care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For any other purpose determined appropriate by the Secretary.

(C) Limitations on data use

A PDP sponsor shall not use data provided to the sponsor pursuant to subparagraph (A) for any of the following purposes:

(i) To inform coverage determinations under this part.

(ii) To conduct retroactive reviews of medically accepted indications determinations.

(iii) To facilitate enrollment changes to a different prescription drug plan or an MA–PD plan offered by the same parent organization.

(iv) To inform marketing of benefits.

(v) For any other purpose that the Secretary determines is necessary to include in order to protect the identity of individuals entitled to, or enrolled for, benefits under this subchapter and to protect the security of personal health information.

(D) Data described

The data described in this clause are standardized extracts (as determined by the Secretary) of claims data under parts A and B for items and services furnished under such parts for time periods specified by the Secretary. Such data shall include data as current as practicable.

(d) Consumer satisfaction surveys

In order to provide for comparative information under section 1395w–101(c)(3)(A)(v) of this title, the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

(e) Electronic prescription program

(1) Application of standards

As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

(2) Program requirements

Consistent with uniform standards established under paragraph (3)—

(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists

An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) Application to medical history information

Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) Limitations

Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) Timing

To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(E) Electronic prior authorization

(i) In general

Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—

(I) a prior authorization request from the prescribing health care professional for coverage of a covered part D drug for a part D eligible individual enrolled in a part D plan (as defined in section 1395w–133(a)(5) of this title) to the PDP sponsor or Medicare Advantage organization offering such plan; and

(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.

(ii) Electronic transmission

(I) Exclusions

For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).

(II) Standards

In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

(III) Application

Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.

(3) Standards

(A) In general

The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) Objectives

Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) Design criteria

Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of subchapter XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) Permitting use of appropriate messaging

Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

(E) Permitting patient designation of dispensing pharmacy

(i) In general

Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) No change in benefits

Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) Development, promulgation, and modification of standards

(A) Initial standards

Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or

modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 242k(k) of this title) under subparagraph (B).

(B) Role of NCVHS

The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1320d(8) of this title)[4]

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) Pilot project to test initial standards

(i) In general

During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) Exception

Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

(iii) Voluntary participation of physicians and pharmacies

In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) Evaluation and report

(I) Evaluation

The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(II) Report to Congress

Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) Final standards

Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) Relation to State laws

The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) Establishment of safe harbor

The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1320a–7b(b) of this title and an exception to the prohibition under subsection (a)(1) of section 1395nn of this title with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1395nn(h)(4) of this title), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(7) Requirement of e-prescribing for controlled substances

(A) In general

Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

(B) Exception for certain circumstances

The Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

(i) a prescription issued when the practitioner and dispensing pharmacy are the same entity;

(ii) a prescription issued that cannot be transmitted electronically under the most

[4] So in original. Probably should be followed by a period.

recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

(iii) a prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

(v) a prescription issued by a practitioner prescribing a drug under a research protocol;

(vi) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

(vii) a prescription issued by a practitioner—

(I) for an individual who receives hospice care under this subchapter; and

(II) that is not covered under the hospice benefit under this subchapter; and

(viii) a prescription issued by a practitioner for an individual who is—

(I) a resident of a nursing facility (as defined in section 1396r(a) of this title); and

(II) dually eligible for benefits under this subchapter and subchapter XIX.

(C) Dispensing

(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations.

(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

(D) Enforcement

The Secretary shall, through rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).

(f) Grievance mechanism

Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1395w–22(f) of this title.

(g) Coverage determinations and reconsiderations

(1) Application of coverage determination and reconsideration provisions

A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1395w–22(g) of this title with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

(2) Request for a determination for the treatment of tiered formulary drug

In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

(h) Appeals

(1) In general

Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1395w–22(g) of this title with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D

eligible individual shall be entitled to bring such an appeal.

(2) Limitation in cases on nonformulary determinations

A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

(3) Treatment of nonformulary determinations

If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1395w–102(b)(4)(C)(i) of this title.

(i) Privacy, confidentiality, and accuracy of enrollee records

The provisions of section 1395w–22(h) of this title shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

(j) Treatment of accreditation

Subparagraph (A) of section 1395w–22(e)(4) of this title (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

(1) Subsection (b) of this section (relating to access to covered part D drugs).

(2) Subsection (c) of this section (including quality assurance and medication therapy management).

(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

(k) Public disclosure of pharmaceutical prices for equivalent drugs

(1) In general

A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) Timing of notice

(A) In general

Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) Waiver

The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

***(l)* Requirements with respect to sales and marketing activities**

The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1395w–21(h)(4)(C) of this title on conducting activities described in section 1395w–21(j)(1) of this title.

(2) The requirement under section 1395w–21(h)(4)(D) of this title to conduct activities described in section 1395w–21(j)(2) of this title in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1395w–21(h)(6) of this title.

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1395w–21(h)(7) of this title.

(m) Prohibition on limiting certain information on drug prices

A PDP sponsor and a Medicare Advantage organization shall ensure that each prescription drug plan or MA–PD plan offered by the sponsor or organization does not restrict a pharmacy that dispenses a prescription drug or biological from informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug or biological to the enrollee under the plan and a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage.

(n) Program integrity transparency measures

For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1395w–28(i) of this title.

***(o)* Real-time benefit information**

(1) In general

After the Secretary has adopted a standard under paragraph (3) for electronic real-time benefit tools, and at a time determined appropriate by the Secretary, a PDP sponsor of a prescription drug plan shall implement one or more of such tools that meet the requirements described in paragraph (2).

(2) Requirements

For purposes of paragraph (1), the requirements described in this paragraph, with respect to an electronic real-time benefit tool, are that the tool is capable of—

(A) integrating with electronic prescribing and electronic health record systems of prescribing health care professionals for the transmission of formulary and benefit infor-

mation in real time to such professionals; and

(B) with respect to a covered part D drug, transmitting such information specific to an individual enrolled in a prescription drug plan, including the following:

(i) A list of any clinically-appropriate alternatives to such drug included in the formulary of such plan.

(ii) Cost-sharing information and the negotiated price for such drug and such alternatives at multiple pharmacy options, including the individual's preferred pharmacy and, as applicable, other retail pharmacies and a mail order pharmacy.

(iii) The formulary status of such drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alternatives included in the formulary of such plan.

(3) Standards

In order to be treated (for purposes of this subsection) as an electronic real-time benefit tool described in paragraph (1), such tool shall comply with technical standards adopted by the Secretary in consultation with the National Coordinator for Health Information Technology through notice and comment rulemaking. Such technical standards adopted by the Secretary shall be developed by a standards development organization, such as the National Council for Prescription Drug Programs, that consults with stakeholders such as PDP sponsors, Medicare Advantage organizations, beneficiary advocates, health care professionals, and health information technology software vendors.

(4) Rules of construction

Nothing in this subsection shall be construed—

(A) to prohibit the application of paragraph (b)(7) of section 423.160 of title 42, Code of Federal Regulations, as is to be added to such section pursuant to the final rule published in the Federal Register on May 23, 2019, and titled ''Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses'' (84 Fed. Reg. 23832 through 23884); or

(B) to allow a PDP sponsor to use a real-time benefit tool to steer an individual, without the consent of the individual, to a particular pharmacy or pharmacy type over their preferred pharmacy or pharmacy type nor prohibit the designation of an individual's preferred pharmacy under such tool.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–4, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2082; amended Pub. L. 110–275, title I, §§103(a)(2), (b)(2), (c)(2), (d)(2), 176, July 15, 2008, 122 Stat. 2499–2501, 2581; Pub. L. 111–148, title III, §§3307(a), 3310(a), 3312(a), title X, §10328(a), Mar. 23, 2010, 124 Stat. 471, 475, 476, 964; Pub. L. 114–10, title V, §507, Apr. 16, 2015, 129 Stat. 168; Pub. L. 114–198, title VII, §704(a)(1), (2), (b), July 22, 2016, 130 Stat. 742–748; Pub. L. 115–123, div. E, title III, §50354, Feb. 9, 2018, 132 Stat. 213; Pub. L. 115–262, §2(a), Oct. 10, 2018, 132 Stat. 3670; Pub. L. 115–271, title II, §§2003(a), 2004, 2006, 2007(a), title VI, §§6062, 6063(c)–6065, 6102, 6103(b), Oct. 24, 2018, 132 Stat. 3926, 3928, 3930, 3986, 3989, 4004, 4005; Pub. L. 116–136, div. A, title III, §3714(a), Mar. 27, 2020, 134 Stat. 424; Pub. L. 116–260, div. CC, title I, §119(a), Dec. 27, 2020, 134 Stat. 2951.)

REFERENCES IN TEXT

Section 6052 of the SUPPORT for Patients and Communities Act, referred to in subsec. (c)(4)(D)(v)(I), is section 6052 of title VI of Pub. L. 115–271, which is set out as a note under this section.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsecs. (c)(5)(J) and (e)(2)(C), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

Section 119 of the Medicare Improvements for Patients and Providers Act of 2008, referred to in subsec. (c)(5)(K)(ii), is section 119 of Pub. L. 110–275, which is set out as a note under section 1395b–3 of this title.

AMENDMENTS

2020—Subsec. (b)(4). Pub. L. 116–136 added par. (4).

Subsecs. (m), (n). Pub. L. 116–260, §119(a)(1), redesignated subsec. (m), relating to program integrity transparency measures, as (n).

Subsec. (*o*). Pub. L. 116–260, §119(a)(2), added subsec. (*o*).

2018—Subsec. (a)(1)(A). Pub. L. 115–271, §6102(1), inserted '', subject to subparagraph (C),'' before ''including''.

Subsec. (a)(1)(B)(vi). Pub. L. 115–271, §6102(2), added cl. (vi).

Subsec. (a)(1)(C). Pub. L. 115–271, §6102(3), added subpar. (C).

Subsec. (c)(1)(F). Pub. L. 115–271, §2004(1), added subpar. (F).

Subsec. (c)(2)(A)(ii). Pub. L. 115–271, §6064, substituted ''are the following:'' for ''are part D eligible individuals who—'' in introductory provisions, added subcls. (I) and (II), redesignated former subcls. (I) to (III) as items (aa) to (cc), respectively, of subcl. (I), and realigned margins.

Subsec. (c)(2)(B). Pub. L. 115–271, §6103(b), struck out ''may include elements that promote'' after ''program'' in introductory provisions, added cls. (i) and (ii), redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (i), and realigned margins.

Subsec. (c)(4)(D). Pub. L. 115–271, §6065, added subpar. (D).

Subsec. (c)(5)(A). Pub. L. 115–271, §2004(2), inserted ''(and for plan years beginning on or after January 1, 2022, a PDP sponsor shall)'' after ''A PDP sponsor may''.

Subsec. (c)(5)(B)(ii)(III), (iii)(IV). Pub. L. 115–271, §2007(a)(1), substituted '', including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution'' for ''and the option of an automatic escalation to external review''.

Subsec. (c)(5)(C)(i). Pub. L. 115–271, §2006(1), substituted ''Except as provided in clause (v), for purposes'' for ''For purposes''.

Subsec. (c)(5)(C)(v). Pub. L. 115–271, §2006(2), added cl. (v).

Subsec. (c)(5)(E). Pub. L. 115–271, §2007(a)(2), substituted ''and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution.'' for ''and the option of an automatic escalation to external review to the extent provided by the Secretary.''

Subsec. (c)(6). Pub. L. 115–123 added par. (6) relating to providing prescription drug plans with parts A and B

claims data to promote the appropriate use of medications and improve health outcomes.

Subsec. (e)(2)(E). Pub. L. 115–271, §6062, added subpar. (E).

Subsec. (e)(7). Pub. L. 115–271, §2003(a), added par. (7).

Subsec. (m). Pub. L. 115–271, §6063(c), added subsec. (m) relating to program integrity transparency measures.

Pub. L. 115–262 added subsec. (m) relating to prohibition on limiting certain information on drug prices.

2016—Subsec. (a)(1)(B)(v). Pub. L. 114–198, §704(a)(2), added cl. (v).

Subsec. (c)(1)(E). Pub. L. 114–198, §704(b)(1), added subpar. (E).

Subsec. (c)(5). Pub. L. 114–198, §704(a)(1), added par. (5).

Subsec. (c)(6). Pub. L. 114–198, §704(b)(2), added par. (6).

2015—Subsec. (c)(4). Pub. L. 114–10 added par. (4).

2010—Subsec. (b)(3)(G). Pub. L. 111–148, §3307(a), amended subpar. (G) generally. Prior to amendment, subpar. (G) related to required inclusion of drugs in certain categories and classes.

Subsec. (b)(3)(H). Pub. L. 111–148, §3312(a), added subpar. (H).

Subsec. (c)(2)(C) to (G). Pub. L. 111–148, §10328(a), added subpars. (C) to (E) and redesignated former subpars. (C) to(E) as (E) to (G), respectively.

Subsec. (c)(3). Pub. L. 111–148, §3310(a), added par. (3).

2008—Subsec. (b)(3)(C)(i). Pub. L. 110–275, §176(1), substituted ''Subject to subparagraph (G), the formulary'' for ''The formulary''.

Subsec. (b)(3)(G). Pub. L. 110–275, §176(2), added subpar. (G).

Subsec. (*l*). Pub. L. 110–275, §103(a)(2), added subsec. (*l*).

Subsec. (*l*)(2). Pub. L. 110–275, §103(b)(2), added par. (2).

Subsec. (*l*)(3). Pub. L. 110–275, §103(c)(2), added par. (3).

Subsec. (*l*)(4). Pub. L. 110–275, §103(d)(2), added par. (4).

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–271, title II, §2003(b), Oct. 24, 2018, 132 Stat. 3928, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to coverage of drugs prescribed on or after January 1, 2021.''

Pub. L. 115–271, title II, §2007(b), Oct. 24, 2018, 132 Stat. 3931, provided that: ''The amendments made by subsection (a) [amending this section] shall apply beginning not later [than] January 1, 2021.''

Pub. L. 115–262, §2(b), Oct. 10, 2018, 132 Stat. 3671, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to plan years beginning on or after January 1, 2020.''

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114–198 applicable to prescription drug plans (and MA–PD plans) for plan years beginning on or after Jan. 1, 2019, see section 704(g)(1) of Pub. L. 114–198, set out as a note under section 1395w–101 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3307(b), Mar. 23, 2010, 124 Stat. 472, provided that: ''The amendments made by this section [amending this section] shall apply to plan year 2011 and subsequent plan years.''

Pub. L. 111–148, title III, §3310(b), Mar. 23, 2010, 124 Stat. 475, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to plan years beginning on or after January 1, 2012.''

Pub. L. 111–148, title III, §3312(b), Mar. 23, 2010, 124 Stat. 476, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to exceptions and appeals on or after January 1, 2012.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 103(a)(2) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 103(a)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

Amendment by section 103(b)(2) of Pub. L. 110–275 effective on a date specified by the Secretary (but in no case later than Nov. 15, 2008), see section 103(b)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

Amendment by section 103(d)(2) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 103(d)(3) of Pub. L. 110–275, set out as a note under section 1395w–21 of this title.

RULE OF CONSTRUCTION

Pub. L. 111–148, title X, §10328(b), Mar. 23, 2010, 124 Stat. 965, provided that: ''Nothing in this section [amending this section] shall limit the authority of the Secretary of Health and Human Services to modify or broaden requirements for a medication therapy management program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] or to study new models for medication therapy management through the Center for Medicare and Medicaid Innovation under section 1115A of such Act [42 U.S.C. 1315a], as added by section 3021 [of Pub. L. 111–148].''

IMPLEMENTATION OF 2020 AMENDMENT

Pub. L. 116–136, div. A, title III, §3714(b), Mar. 27, 2020, 134 Stat. 424, provided that: ''Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendment made by this section [amending this section] by program instruction or otherwise.''

UPDATE OF BIOMETRIC COMPONENT OF MULTIFACTOR AUTHENTICATION

Pub. L. 115–271, title II, §2003(c), Oct. 24, 2018, 132 Stat. 3928, provided that: ''Not later than 1 year after the date of enactment of this Act [Oct. 24, 2018], the Attorney General shall update the requirements for the biometric component of multifactor authentication with respect to electronic prescriptions of controlled substances.''

GRANTS TO PROVIDE TECHNICAL ASSISTANCE TO OUTLIER PRESCRIBERS OF OPIOIDS

Pub. L. 115–271, title VI, §6052, Oct. 24, 2018, 132 Stat. 3985, provided that:

''(a) GRANTS AUTHORIZED.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall, through the Centers for Medicare & Medicaid Services, award grants, contracts, or cooperative agreements to eligible entities for the purposes described in subsection (b).

''(b) USE OF FUNDS.—Grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to support eligible entities through technical assistance—

''(1) to educate and provide outreach to outlier prescribers of opioids about best practices for prescribing opioids;

''(2) to educate and provide outreach to outlier prescribers of opioids about non-opioid pain management therapies; and

''(3) to reduce the amount of opioid prescriptions prescribed by outlier prescribers of opioids.

''(c) APPLICATION.—Each eligible entity seeking to receive a grant, contract, or cooperative agreement under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

''(d) GEOGRAPHIC DISTRIBUTION.—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall prioritize establishing technical assistance resources in each State.

''(e) DEFINITIONS.—In this section:

''(1) ELIGIBLE ENTITY.—The term 'eligible entity' means—

''(A) an organization—

''(i) that has demonstrated experience providing technical assistance to health care professionals on a State or regional basis; and

''(ii) that has at least—

''(I) one individual who is a representative of consumers on its governing body; and

''(II) one individual who is a representative of health care providers on its governing body; or

''(B) an entity that is a quality improvement entity with a contract under part B of title XI of the Social Security Act (42 U.S.C. 1320c et seq.).

''(2) OUTLIER PRESCRIBER OF OPIOIDS.—The term 'outlier prescriber of opioids' means, with respect to a period, a prescriber identified by the Secretary under subparagraph (D)(ii) of section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–104(c)(4)), as added by section 6065 of this Act, to be an outlier prescriber of opioids for such period.

''(3) PRESCRIBERS.—The term 'prescriber' means any health care professional, including a nurse practitioner or physician assistant, who is licensed to prescribe opioids by the State or territory in which such professional practices.

''(f) FUNDING.—For purposes of implementing this section, $75,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to remain available until expended.''

GRANTS TO PHYSICIANS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS

Pub. L. 108–173, title I, § 108, Dec. 8, 2003, 117 Stat. 2172, provided that:

''(a) IN GENERAL.—The Secretary [of Health and Human Services] is authorized to make grants to physicians for the purpose of assisting such physicians to implement electronic prescription drug programs that comply with the standards promulgated or modified under section 1860D–4(e) of the Social Security Act [42 U.S.C. 1395w–104(e)], as inserted by section 101(a).

''(b) AWARDING OF GRANTS.—

''(1) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted and approved in a time, manner, and form specified by the Secretary.

''(2) CONSIDERATIONS AND PREFERENCES.—In awarding grants under this section, the Secretary shall—

''(A) give special consideration to physicians who serve a disproportionate number of medicare patients; and

''(B) give preference to physicians who serve a rural or underserved area.

''(3) LIMITATION ON GRANTS.—Only 1 grant may be awarded under this section with respect to any physician or group practice of physicians.

''(c) TERMS AND CONDITIONS.—

''(1) IN GENERAL.—Grants under this section shall be made under such terms and conditions as the Secretary specifies consistent with this section.

''(2) USE OF GRANT FUNDS.—Funds provided under grants under this section may be used for any of the following:

''(A) For purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

''(B) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

''(C) Providing education and training to eligible physician staff on the use of technology to implement the electronic transmission of prescription and patient information.

''(3) PROVISION OF INFORMATION.—As a condition for the awarding of a grant under this section, an applicant shall provide to the Secretary such information as the Secretary may require in order to—

''(A) evaluate the project for which the grant is made; and

''(B) ensure that funding provided under the grant is expended only for the purposes for which it is made.

''(4) AUDIT.—The Secretary shall conduct appropriate audits of grants under this section.

''(5) MATCHING REQUIREMENT.—The applicant for a grant under this section shall agree, with respect to the costs to be incurred by the applicant in implementing an electronic prescription drug program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs. Non-Federal contributions under the previous sentence may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009.''

SUBPART 2—PRESCRIPTION DRUG PLANS; PDP SPONSORS; FINANCING

§ 1395w–111. PDP regions; submission of bids; plan approval

(a) Establishment of PDP regions; service areas

(1) Coverage of entire PDP region

The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

(2) Establishment of PDP regions

(A) In general

The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1395w–27a(a)(2) of this title.

(B) Relation to MA regions

To the extent practicable, PDP regions shall be the same as MA regions under section 1395w–27a(a)(2) of this title. The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

(C) Authority for territories

The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

(3) National plan

Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

(b) Submission of bids, premiums, and related information

(1) In general

A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1395w–24(a) of this title is submitted by an MA organization under paragraph (1) of such section.

(2) Information described

The information described in this paragraph is information on the following:

(A) Coverage provided

The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

(B) Actuarial value

The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1395w–115(c)(1)(A) of this title (as specified by the Secretary).

(C) Bid

Information on the bid, including an actuarial certification of—

(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

(iii) assumptions regarding the reinsurance subsidy payments provided under section 1395w–115(b) of this title subtracted from the actuarial value to produce such bid; and

(iv) administrative expenses assumed in the bid.

(D) Service area

The service area for the plan.

(E) Level of risk assumed

(i) In general

Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

(ii) Risk levels described

A modification of risk level under this clause may consist of one or more of the following:

(I) Increase in Federal percentage assumed in initial risk corridor

An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1395w–115(e)(2) of this title. In no case shall the application of previous sentence prevent the application of a higher percentage under section 1395w–115(e)(2)(B)(iii)[1] of this title.

(II) Increase in Federal percentage assumed in second risk corridor

An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1395w–115(e)(2) of this title.

(III) Decrease in size of risk corridors

A decrease in the threshold risk percentages specified in section 1395w–115(e)(3)(C) of this title.

(F) Additional information

Such other information as the Secretary may require to carry out this part.

(3) Paperwork reduction for offering of prescription drug plans nationally or in multi-region areas

The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

(c) Actuarial valuation

(1) Processes

For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

(A) an actuarial valuation of standard prescription drug coverage under section 1395w–102(b) of this title;

(B) actuarial valuations relating to alternative prescription drug coverage under section 1395w–102(c)(1) of this title;

(C) an actuarial valuation of the reinsurance subsidy payments under section 1395w–115(b) of this title;

(D) the use of generally accepted actuarial principles and methodologies; and

(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

(2) Accounting for drug utilization

Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

(3) Responsibilities

(A) Plan responsibilities

PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

(B) Use of outside actuaries

Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

(d) Review of information and negotiation

(1) Review of information

The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

(2) Negotiation regarding terms and conditions

Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

[1] See References in Text note below.

(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5.

(3) Rejection of bids

Paragraph (5)(C) of section 1395w–24(a) of this title shall apply with respect to bids submitted by a PDP sponsor under subsection (b) in the same manner as such paragraph applies to bids submitted by an MA organization under such section 1395w–24(a) of this title.

(e) Approval of proposed plans

(1) In general

After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

(2) Requirements for approval

The Secretary may approve a prescription drug plan only if the following requirements are met:

(A) Compliance with requirements

The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

(B) Actuarial determinations

The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1395w–102(c) of this title.

(C) Application of FEHBP standard

(i) In general

The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e–1(8)(C) of this title) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1395w–115(b) of this title.

(ii) Supplemental coverage

The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1395w–102(a)(2) of this title is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e–1(8)(C) of this title) for such coverage under the plan.

(D) Plan design

(i) In general

The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

(ii) Use of categories and classes in formularies

The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

(f) Application of limited risk plans

(1) Conditions for approval of limited risk plans

The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1395w–103(a) of this title would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

(2) Rules

The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

(A) Limited exercise of authority

Only the minimum number of such plans may be approved in order to meet the access requirements under section 1395w–103(a) of this title.

(B) Maximizing assumption of risk

The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

(C) No full underwriting for limited risk plans

In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

(3) Acceptance of all full risk contracts

There shall be no limit on the number of full risk plans that are approved under subsection (e).

(4) Risk-plans defined

For purposes of this subsection:

(A) Limited risk plan

The term ''limited risk plan'' means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

(B) Full risk plan

The term ''full risk plan'' means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

(g) Guaranteeing access to coverage

(1) Solicitation of bids

(A) In general

Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

(B) Acceptance of bids

(i) In general

Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

(ii) Limitation of 1 plan for all fallback service areas in a PDP region

With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

(iii) Competitive procedures

Competitive procedures (as defined in section 132 of title 41) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1395kk–1 of this title shall apply to a contract under this section in the same manner as they apply to a contract under such section.

(iv) Timing

The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

(V)[2] No national fallback plan

The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

(2) Eligible fallback entity

For purposes of this section, the term ''eligible fallback entity'' means, with respect to all fallback service areas in a PDP region for a contract period, an entity that—

(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

(B) does not submit a bid under subsection (b) for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Fallback service area

For purposes of this subsection, the term ''fallback service area'' means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1395w–103(a) of this title will not be met for part D eligible individuals residing in the area for the year.

(4) Fallback prescription drug plan

For purposes of this part, the term ''fallback prescription drug plan'' means a prescription drug plan that—

(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1395w–102(a)(1)(A) of this title and does not include any supplemental prescription drug coverage; and

(B) meets such other requirements as the Secretary may specify.

(5) Payments under the contract

(A) In general

A contract entered into under this subsection shall provide for—

(i) payment for the actual costs (taking into account negotiated price concessions described in section 1395w–102(d)(1)(B) of this title) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

(B) Performance measures

The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

(i) Costs

The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

(ii) Quality programs

The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

(iii) Customer service

The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

[2] So in original. Probably should be ''(v)''.

(iv) Benefit administration and claims adjudication

The entity provides efficient and effective benefit administration and claims adjudication.

(6) Monthly beneficiary premium

Except as provided in section 1395w–113(b) of this title (relating to late enrollment penalty) and subject to section 1395w–114 of this title (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(7) General contract terms and conditions

(A) In general

Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

(B) Period of contract

(i) In general

Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

(ii) Limitation

A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

(C) Entity not permitted to market or brand fallback prescription drug plans

An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

(h) Annual report on use of limited risk plans and fallback plans

The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection[3] (f).

[3] So in original.

(i) Noninterference

In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

(j) Coordination of benefits

A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1395w–133 and 1395w–134 of this title to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–11, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2092; amended Pub. L. 111–148, title III, §3209(b), Mar. 23, 2010, 124 Stat. 460.)

REFERENCES IN TEXT

Section 1395w–115(e)(2)(B)(iii) of this title, referred to in subsec. (b)(2)(E)(ii)(I), was in the original ''section 1869D–15(e)(2)(B)(iii)'', and was translated as reading ''section 1860D–15(e)(2)(B)(iii)'', meaning 1860D–15(e)(2)(B)(iii) of the Social Security Act, to reflect the probable intent of Congress, because the Social Security Act does not contain a section 1869D–15 and section 1395w–115(e)(2)(B)(iii) of this title provides for an application of a higher percentage for years 2006 and 2007.

CODIFICATION

In subsec. (g)(1)(B)(iii), ''section 132 of title 41'' substituted for ''section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2010—Subsec. (d)(3). Pub. L. 111–148 added par. (3).

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–148 applicable to bids submitted for contract years beginning on or after Jan. 1, 2011, see section 3209(c) of Pub. L. 111–148, set out as a note under section 1395w–24 of this title.

STUDY REGARDING REGIONAL VARIATIONS IN PRESCRIPTION DRUG SPENDING

Pub. L. 108–173, title I, §107(a), Dec. 8, 2003, 117 Stat. 2169, provided that:

''(1) IN GENERAL.—The Secretary [of Health and Human Services] shall conduct a study that examines variations in per capita spending for covered part D drugs under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] among PDP regions and, with respect to such spending, the amount of such variation that is attributable to—

''(A) price variations (described in section 1860D–15(c)(2) of such Act [42 U.S.C. 1395w–115(c)(2)]); and

''(B) differences in per capita utilization that is not taken into account in the health status risk adjustment provided under section 1860D–15(c)(1) of such Act [42 U.S.C. 1395w–115(c)(1)].

''(2) REPORT AND RECOMMENDATIONS.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include—

''(A) information regarding the extent of geographic variation described in paragraph (1)(B);

''(B) an analysis of the impact on direct subsidies under section 1860D–15(a)(1) of the Social Security Act [42 U.S.C. 1395w–115(a)(1)] in different PDP regions if such subsidies were adjusted to take into account the variation described in subparagraph (A); and

''(C) recommendations regarding the appropriateness of applying an additional geographic adjustment factor under section 1860D–15(c)(2) [42 U.S.C. 1395w–115(c)(2)] that reflects some or all of the variation described in subparagraph (A).''

§ 1395w–112. Requirements for and contracts with prescription drug plan (PDP) sponsors

(a) General requirements

Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) Licensure

Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) Assumption of financial risk for unsubsidized coverage

(A) In general

Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1395w–115(b) of this title.

(B) Reinsurance permitted

The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) Solvency for unlicensed sponsors

In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) Contract requirements

(1) In general

The Secretary shall not permit the enrollment under section 1395w–101 of this title in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1395w–114 or 1395w–115 of this title, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) Limitation on entities offering fallback prescription drug plans

The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1395w–111(g) of this title for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Incorporation of certain medicare advantage contract requirements

Except as otherwise provided, the following provisions of section 1395w–27 of this title shall apply to contracts under this section in the same manner as they apply to contracts under section 1395w–27(a) of this title:

(A) Minimum enrollment

Paragraphs (1) and (3) of section 1395w–27(b) of this title, except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) Contract period and effectiveness

Section 1395w–27(c) of this title, except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1395w–23 of this title shall be deemed payment amounts under section 1395w–115 of this title.

(C) Protections against fraud and beneficiary protections

Section 1395w–27(d) of this title.

(D) Additional contract terms

Section 1395w–27(e) of this title; except that section 1395w–27(e)(2) of this title shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1395w–27(e)(1) of this title to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate); and

(ii) shall be made available to Congressional[1] support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional[1] oversight, monitoring, making recommendations, and analysis of the program under this subchapter.

(E) Intermediate sanctions

Section 1395w–27(g) of this title (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1395w–27(g)(1)(B) of this title to section 1395w–24 of this title is deemed a reference to this part.

(F) Procedures for termination

Section 1395w–27(h) of this title.

(4) Prompt payment of clean claims

(A) Prompt payment

(i) In general

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) Clean claim defined

In this paragraph, the term ''clean claim'' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) Date of receipt of claim

In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) Applicable number of calendar days defined

In this paragraph, the term ''applicable number of calendar days'' means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) Interest payment

(i) In general

Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1395w–115(e) of this title.

(ii) Authority not to charge interest

The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) Procedures involving claims

(i) Claim deemed to be clean

A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) Claim determined to not be a clean claim

(I) In general

If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) Determination after submission of additional information

A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) Obligation to pay

A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be

[1] So in original. Probably should not be capitalized.

paid by the PDP sponsor in accordance with subparagraph (A).

(iv) Date of payment of claim

Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) Electronic transfer of funds

A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) Protecting the rights of claimants

(i) In general

Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) Anti-retaliation

Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) Rule of construction

A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this subchapter, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) Submission of claims by pharmacies located in or contracting with long-term care facilities

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) Regular update of prescription drug pricing standard

If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(7) Suspension of payments pending investigation of credible allegations of fraud by pharmacies

(A) In general

Section 1395y(*o*)(1) of this title shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such section applies with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this subchapter. A PDP sponsor shall notify the Secretary regarding the imposition of any payment suspension pursuant to the previous sentence, such as through the secure internet website portal (or other successor technology) established under section 1395w–28(i) of this title.

(B) Rule of construction

Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.

(c) Waiver of certain requirements to expand choice

(1) Authorizing waiver

(A) In general

In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) Application of regional plan waiver rule

In addition to the waiver available under subparagraph (A), the provisions of section 1395w–27a(d) of this title shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) Grounds for approval

(A) In general

The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1395w–25(a)(2) of this title; and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) Special rules

In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1395w–25(a)(2)(B) of this title is

deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) Application of waiver procedures

With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1395w–25(a)(2) of this title shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) References to certain provisions

In applying provisions of section 1395w–25(a)(2) of this title under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1395w–25 of this title shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) Solvency standards for non-licensed entities

(1) Establishment and publication

The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) Compliance with standards

A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1395w–25(c)(2) of this title.

(e) Licensure does not substitute for or constitute certification

The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) Periodic review and revision of standards

(1) In general

Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) Prohibition of State imposition of premium taxes; relation to State laws

The provisions of sections 1395w–24(g) and 1395w–26(b)(3) of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–12, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2099; amended Pub. L. 110–275, title I, §§171(a), 172(a)(1), 173(a), 181, July 15, 2008, 122 Stat. 2578, 2580–2582; Pub. L. 115–271, title II, §2008(a), Oct. 24, 2018, 132 Stat. 3931.)

AMENDMENTS

2018—Subsec. (b)(7). Pub. L. 115–271 added par. (7).

2008—Subsec. (b)(3)(D). Pub. L. 110–275, §181, inserted at end ''Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1395w–27(e)(1) of this title to contracts under this section under the preceding sentence—'' and added cls. (i) and (ii).

Subsec. (b)(4). Pub. L. 110–275, §171(a), added par. (4).

Subsec. (b)(5). Pub. L. 110–275, §172(a)(1), added par. (5).

Subsec. (b)(6). Pub. L. 110–275, §173(a), added par. (6).

EFFECTIVE DATE OF 2018 AMENDMENT

Amendment by section 2008(a) of Pub. L. 115–271 applicable with respect to plan years beginning on or after Jan. 1, 2020, see section 2008(e) of Pub. L. 115–271, set out as a note under section 1395w–27 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 171(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 171(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 172(a)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 172(b) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 173(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 173(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

§ 1395w–113. Premiums; late enrollment penalty

(a) Monthly beneficiary premium

(1) Computation

(A) In general

The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) as adjusted under this paragraph.

(B) Adjustment to reflect difference between bid and national average bid

(i) Above average bid

If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid

amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.

(ii) Below average bid

If for a month the amount of the adjusted national average monthly bid amount for the month exceeds the standardized bid amount, the base beneficiary premium for the month shall be decreased by the amount of such excess.

(iii) Adjusted national average monthly bid amount defined

For purposes of this subparagraph, the term ''adjusted national average monthly bid amount'' means the national average monthly bid amount computed under paragraph (4), as adjusted under section 1395w–115(c)(2) of this title.

(C) Increase for supplemental prescription drug benefits

The base beneficiary premium shall be increased by the portion of the PDP approved bid that is attributable to supplemental prescription drug benefits.

(D) Increase for late enrollment penalty

The base beneficiary premium shall be increased by the amount of any late enrollment penalty under subsection (b).

(E) Decrease for low-income assistance

The monthly beneficiary premium is subject to decrease in the case of a subsidy eligible individual under section 1395w–114 of this title.

(F) Increase based on income

The monthly beneficiary premium shall be increased pursuant to paragraph (7).

(G) Uniform premium

Except as provided in subparagraphs (D), (E), and (F), the monthly beneficiary premium for a prescription drug plan in a PDP region is the same for all part D eligible individuals enrolled in the plan.

(2) Base beneficiary premium

The base beneficiary premium under this paragraph for a prescription drug plan for a month is equal to the product[1]—

(A) the beneficiary premium percentage (as specified in paragraph (3)); and

(B) the national average monthly bid amount (computed under paragraph (4)) for the month.

(3) Beneficiary premium percentage

For purposes of this subsection, the beneficiary premium percentage for any year is the percentage equal to a fraction—

(A) the numerator of which is 25.5 percent; and

(B) the denominator of which is 100 percent minus a percentage equal to—

(i) the total reinsurance payments which the Secretary estimates are payable under section 1395w–115(b) of this title with respect to the coverage year; divided by

(ii) the sum of—

(I) the amount estimated under clause (i) for the year; and

(II) the total payments which the Secretary estimates will be paid to prescription drug plans and MA–PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by the Secretary and enrollees.

(4) Computation of national average monthly bid amount

(A) In general

For each year (beginning with 2006) the Secretary shall compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title. Such average does not take into account the bids submitted for MSA plans, MA private fee-for-service plan, and specialized MA plans for special needs individuals, PACE programs under section 1395eee of this title (pursuant to section 1395w–131(f) of this title), and under reasonable cost reimbursement contracts under section 1395mm(h) of this title (pursuant to section 1395w–131(e) of this title).

(B) Weighted average

(i) In general

The monthly national average monthly bid amount computed under subparagraph (A) for a year shall be a weighted average, with the weight for each plan being equal to the average number of part D eligible individuals enrolled in such plan in the reference month (as defined in section 1395w–27a(f)(4) of this title).

(ii) Special rule for 2006

For purposes of applying this paragraph for 2006, the Secretary shall establish procedures for determining the weighted average under clause (i) for 2005.

(5) Standardized bid amount defined

For purposes of this subsection, the term ''standardized bid amount'' means the following:

(A) Prescription drug plans

(i) Basic coverage

In the case of a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid (as defined in paragraph (6)).

(ii) Supplemental coverage

In the case of a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage.

(B) MA–PD plans

In the case of an MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

[1] So in original. The word ''of'' probably should appear after ''product''.

(6) PDP approved bid defined

For purposes of this part, the term ''PDP approved bid'' means, with respect to a prescription drug plan, the bid amount approved for the plan under this part.

(7) Increase in base beneficiary premium based on income

(A) In general

In the case of an individual whose modified adjusted gross income exceeds the threshold amount applicable under paragraph (2) of section 1395r(i) of this title (including application of paragraph (5) of such section) for the calendar year, the monthly amount of the beneficiary premium applicable under this section for a month after December 2010 shall be increased by the monthly adjustment amount specified in subparagraph (B).

(B) Monthly adjustment amount

The monthly adjustment amount specified in this subparagraph for an individual for a month in a year is equal to the product of—

(i) the quotient obtained by dividing—

(I) the applicable percentage determined under paragraph (3)(C) of section 1395r(i) of this title (including application of paragraph (5) of such section) for the individual for the calendar year reduced by 25.5 percent; by

(II) 25.5 percent; and

(ii) the base beneficiary premium (as computed under paragraph (2)).

(C) Modified adjusted gross income

For purposes of this paragraph, the term ''modified adjusted gross income'' has the meaning given such term in subparagraph (A) of section 1395r(i)(4) of this title, determined for the taxable year applicable under subparagraphs (B) and (C) of such section.

(D) Determination by Commissioner of Social Security

The Commissioner of Social Security shall make any determination necessary to carry out the income-related increase in the base beneficiary premium under this paragraph.

(E) Procedures to assure correct income-related increase in base beneficiary premium

(i) Disclosure of base beneficiary premium

Not later than September 15 of each year beginning with 2010, the Secretary shall disclose to the Commissioner of Social Security the amount of the base beneficiary premium (as computed under paragraph (2)) for the purpose of carrying out the income-related increase in the base beneficiary premium under this paragraph with respect to the following year.

(ii) Additional disclosure

Not later than October 15 of each year beginning with 2010, the Secretary shall disclose to the Commissioner of Social Security the following information for the purpose of carrying out the income-related increase in the base beneficiary premium under this paragraph with respect to the following year:

(I) The modified adjusted gross income threshold applicable under paragraph (2) of section 1395r(i) of this title (including application of paragraph (5) of such section).

(II) The applicable percentage determined under paragraph (3)(C) of section 1395r(i) of this title (including application of paragraph (5) of such section).

(III) The monthly adjustment amount specified in subparagraph (B).

(IV) Any other information the Commissioner of Social Security determines necessary to carry out the income-related increase in the base beneficiary premium under this paragraph.

(F) Rule of construction

The formula used to determine the monthly adjustment amount specified under subparagraph (B) shall only be used for the purpose of determining such monthly adjustment amount under such subparagraph.

(b) Late enrollment penalty

(1) In general

Subject to the succeeding provisions of this subsection, in the case of a part D eligible individual described in paragraph (2) with respect to a continuous period of eligibility, there shall be an increase in the monthly beneficiary premium established under subsection (a) in an amount determined under paragraph (3).

(2) Individuals subject to penalty

A part D eligible individual described in this paragraph is, with respect to a continuous period of eligibility, an individual for whom there is a continuous period of 63 days or longer (all of which in such continuous period of eligibility) beginning on the day after the last date of the individual's initial enrollment period under section 1395w–101(b)(2) of this title and ending on the date of enrollment under a prescription drug plan or MA–PD plan during all of which the individual was not covered under any creditable prescription drug coverage.

(3) Amount of penalty

(A) In general

The amount determined under this paragraph for a part D eligible individual for a continuous period of eligibility is the greater of—

(i) an amount that the Secretary determines is actuarially sound for each uncovered month (as defined in subparagraph (B)) in the same continuous period of eligibility; or

(ii) 1 percent of the base beneficiary premium (computed under subsection (a)(2)) for each such uncovered month in such period.

(B) Uncovered month defined

For purposes of this subsection, the term ''uncovered month'' means, with respect to a part D eligible individual, any month beginning after the end of the initial enrollment period under section 1395w–101(b)(2) of this

title unless the individual can demonstrate that the individual had creditable prescription drug coverage (as defined in paragraph (4)) for any portion of such month.

(4) Creditable prescription drug coverage defined

For purposes of this part, the term ''creditable prescription drug coverage'' means any of the following coverage, but only if the coverage meets the requirement of paragraph (5):

(A) Coverage under prescription drug plan or MA–PD plan

Coverage under a prescription drug plan or under an MA–PD plan.

(B) Medicaid

Coverage under a medicaid plan under subchapter XIX or under a waiver under section 1315 of this title.

(C) Group health plan

Coverage under a group health plan, including a health benefits plan under chapter 89 of title 5 (commonly known as the Federal employees health benefits program), and a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title).

(D) State pharmaceutical assistance program

Coverage under a State pharmaceutical assistance program described in section 1395w–133(b)(1) of this title.

(E) Veterans' coverage of prescription drugs

Coverage for veterans, and survivors and dependents of veterans, under chapter 17 of title 38.

(F) Prescription drug coverage under medigap policies

Coverage under a medicare supplemental policy under section 1395ss of this title that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1395ss(p)(1) of this title).

(G) Military coverage (including TRICARE)

Coverage under chapter 55 of title 10.

(H) Other coverage

Such other coverage as the Secretary determines appropriate.

(5) Actuarial equivalence requirement

Coverage meets the requirement of this paragraph only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1395w–111(c) of this title).

(6) Procedures to document creditable prescription drug coverage

(A) In general

The Secretary shall establish procedures (including the form, manner, and time) for the documentation of creditable prescription drug coverage, including procedures to assist in determining whether coverage meets the requirement of paragraph (5).

(B) Disclosure by entities offering creditable prescription drug coverage

(i) In general

Each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) shall provide for disclosure, in a form, manner, and time consistent with standards established by the Secretary, to the Secretary and part D eligible individuals of whether the coverage meets the requirement of paragraph (5) or whether such coverage is changed so it no longer meets such requirement.

(ii) Disclosure of non-creditable coverage

In the case of such coverage that does not meet such requirement, the disclosure to part D eligible individuals under this subparagraph shall include information regarding the fact that because such coverage does not meet such requirement there are limitations on the periods in a year in which the individuals may enroll under a prescription drug plan or an MA–PD plan and that any such enrollment is subject to a late enrollment penalty under this subsection.

(C) Waiver of requirement

In the case of a part D eligible individual who was enrolled in prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) which is not creditable prescription drug coverage because it does not meet the requirement of paragraph (5), the individual may apply to the Secretary to have such coverage treated as creditable prescription drug coverage if the individual establishes that the individual was not adequately informed that such coverage did not meet such requirement.

(7) Continuous period of eligibility

(A) In general

Subject to subparagraph (B), for purposes of this subsection, the term ''continuous period of eligibility'' means, with respect to a part D eligible individual, the period that begins with the first day on which the individual is eligible to enroll in a prescription drug plan under this part and ends with the individual's death.

(B) Separate period

Any period during all of which a part D eligible individual is entitled to hospital insurance benefits under part A and—

(i) which terminated in or before the month preceding the month in which the individual attained age 65; or

(ii) for which the basis for eligibility for such entitlement changed between section 426(b) of this title and section 426(a) of this title, between 426(b)[2] of this title and sec-

[2] So in original. Probably should be ''section 426(b)''.

tion 426–1 of this title, or between section 426–1 of this title and section 426(a) of this title,

shall be a separate continuous period of eligibility with respect to the individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

(8) Waiver of penalty for subsidy-eligible individuals

In no case shall a part D eligible individual who is determined to be a subsidy eligible individual (as defined in section 1395w–114(a)(3) of this title) be subject to an increase in the monthly beneficiary premium established under subsection (a).

(c) Collection of monthly beneficiary premiums

(1) In general

Subject to paragraphs (2), (3), and (4), the provisions of section 1395w–24(d) of this title shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

(2) Crediting of late enrollment penalty

(A) Portion attributable to increased actuarial costs

With respect to late enrollment penalties imposed under subsection (b), the Secretary shall specify the portion of such a penalty that the Secretary estimates is attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under section 1395w–115(c)(1) of this title or through reinsurance payments under section 1395w–115(b) of this title) as a result of such late enrollment.

(B) Collection through withholding

In the case of a late enrollment penalty that is collected from a part D eligible individual in the manner described in section 1395w–24(d)(2)(A) of this title, the Secretary shall provide that only the portion of such penalty estimated under subparagraph (A) shall be paid to the PDP sponsor or MA organization offering the part D plan in which the individual is enrolled.

(C) Collection by plan

In the case of a late enrollment penalty that is collected from a part D eligible individual in a manner other than the manner described in section 1395w–24(d)(2)(A) of this title, the Secretary shall establish procedures for reducing payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of such penalty less the portion of such penalty estimated under subparagraph (A).

(3) Fallback plans

In applying this subsection in the case of a fallback prescription drug plan, paragraph (2) shall not apply and the monthly beneficiary premium shall be collected in the manner specified in section 1395w–24(d)(2)(A) of this title (or such other manner as may be provided under section 1395s of this title in the case of monthly premiums under section 1395r of this title).

(4) Collection of monthly adjustment amount

(A) In general

Notwithstanding any provision of this subsection or section 1395w–24(d)(2) of this title, subject to subparagraph (B), the amount of the income-related increase in the base beneficiary premium for an individual for a month (as determined under subsection (a)(7)) shall be paid through withholding from benefit payments in the manner provided under section 1395s of this title.

(B) Agreements

In the case where the monthly benefit payments of an individual that are withheld under subparagraph (A) are insufficient to pay the amount described in such subparagraph, the Commissioner of Social Security shall enter into agreements with the Secretary, the Director of the Office of Personnel Management, and the Railroad Retirement Board as necessary in order to allow other agencies to collect the amount described in subparagraph (A) that was not withheld under such subparagraph.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–13, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2102; amended Pub. L. 110–275, title I, §114(a)(1), July 15, 2008, 122 Stat. 2506; Pub. L. 111–148, title III, §3308(a), (b)(1), Mar. 23, 2010, 124 Stat. 472, 474.)

AMENDMENTS

2010—Subsec. (a)(1)(F), (G). Pub. L. 111–148, §3308(b)(1), added subpar. (F), redesignated former subpar. (F) as (G), and substituted ''(D), (E), and (F)'' for ''(D) and (E)'' in subpar. (G).

Subsec. (a)(7). Pub. L. 111–148, §3308(a)(1), added par. (7).

Subsec. (c)(1). Pub. L. 111–148, §3308(a)(2)(A), substituted ''(2), (3), and (4)'' for ''(2) and (3)''.

Subsec. (c)(4). Pub. L. 111–148, §3308(a)(2)(B), added par. (4).

2008—Subsec. (b)(8). Pub. L. 110–275 added par. (8).

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §114(b), July 15, 2008, 122 Stat. 2507, provided that: ''The amendments made by this section [amending this section and section 1395w–114 of this title] shall apply to subsidies for months beginning with January 2009.''

§ 1395w–114. Premium and cost-sharing subsidies for low-income individuals

(a) Income-related subsidies for individuals with income up to 150 percent of poverty line

(1) Individuals with income below 135 percent of poverty line

In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) or who is covered under this paragraph under paragraph

(3)(B)(i), the individual is entitled under this section to the following:

(A) Full premium subsidy

An income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).

(B) Elimination of deductible

A reduction in the annual deductible applicable under section 1395w–102(b)(1) of this title to $0.

(C) Continuation of coverage above the initial coverage limit

The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w–102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold

(i) Institutionalized individuals

In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1396a(q)(1)(B) of this title) or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1396b(m) of this title or under section 1396u–2 of this title, the elimination of any beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title).

(ii) Lowest income dual eligible individuals

In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of a copayment amount that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396r–8(k)(7)(A)(i) of this title) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

(iii) Other individuals

In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of a copayment amount that does not exceed the copayment amount specified under section 1395w–102(b)(4)(A)(i)(I) of this title for the drug and year involved.

(E) Elimination of cost-sharing above annual out-of-pocket threshold

The elimination of any cost-sharing imposed under section 1395w–102(b)(4)(A) of this title.

(2) Other individuals with income below 150 percent of poverty line

In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) Sliding scale premium subsidy

An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

(B) Reduction of deductible

A reduction in the annual deductible applicable under section 1395w–102(b)(1) of this title to $50.

(C) Continuation of coverage above the initial coverage limit

The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w–102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold

The substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of coinsurance of ''15 percent'' instead of coinsurance of ''25 percent'' in section 1395w–102(b)(2) of this title.

(E) Reduction of cost-sharing above annual out-of-pocket threshold

Subject to subsection (c), the substitution for the cost-sharing imposed under section 1395w–102(b)(4)(A) of this title of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified

under section 1395w–102(b)(4)(A)(i)(I) of this title for the drug and year involved.

(3) Determination of eligibility

(A) Subsidy eligible individual defined

For purposes of this part, subject to subparagraph (F), the term ''subsidy eligible individual'' means a part D eligible individual who—

(i) is enrolled in a prescription drug plan or MA–PD plan;

(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and

(iii) meets the resources requirement described in subparagraph (D) or (E).

(B) Determinations

(i) In general

The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under subchapter XIX for the State under section 1396u–5(a) of this title or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) Effective period

Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

(iii) Redeterminations and appeals through medicaid

Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under subchapter XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such subchapter.

(iv) Redeterminations and appeals through Commissioner

With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

(I) redeterminations shall be made at such time or times as may be provided by the Commissioner;

(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1383(c)(1)(A) of this title; and

(III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 405 of this title.

(v) Treatment of medicaid beneficiaries

Subject to subparagraph (F), the Secretary—

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1396u–5(c)(6) of this title) or who are recipients of supplemental security income benefits under subchapter XVI shall be treated as subsidy eligible individuals described in paragraph (1); and

(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under subchapter XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1396a(a)(10)(E) of this title are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(vi) Special rule for widows and widowers

Notwithstanding the preceding provisions of this subparagraph, in the case of an individual whose spouse dies during the effective period for a determination or redetermination that has been made under this subparagraph, such effective period shall be extended through the date that is 1 year after the date on which the determination or redetermination would (but for the application of this clause) otherwise cease to be effective.

(C) Income determinations

For purposes of applying this section—

(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1396d(p)(1)(B) of this title, without regard to the application of section 1396a(r)(2) of this title and except that support and maintenance furnished in kind shall not be counted as income; and

(ii) the term ''poverty line'' has the meaning given such term in section 9902(2) of this title, including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1396a(r)(2) of this title for the determination of eligibility for medical assistance under subchapter XIX.

(D) Resource standard applied to full low-income subsidy to be based on three times SSI resource standard

The resources requirement of this subparagraph is that an individual's resources (as determined under section 1382b of this title for purposes of the supplemental security in-

come program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and

(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(E) Alternative resource standard

(i) In general

The resources requirement of this subparagraph is that an individual's resources (as determined under section 1382b of this title for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(ii) Use of simplified application form and process

The Secretary, jointly with the Commissioner of Social Security, shall—

(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

(II) provide such form to States.

(iii) Documentation and safeguards

Under such process—

(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) Methodology flexibility

The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1396d(p) of this title so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) Treatment of territorial residents

In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1396u–5(e) of this title.

(G) Life insurance policy exclusion

In determining the resources of an individual (and the eligible spouse of the individual, if any) under section 1382b of this title for purposes of subparagraphs (D) and (E) no part of the value of any life insurance policy shall be taken into account.

(4) Indexing dollar amounts

(A) Copayment for lowest income dual eligible individuals

The dollar amounts applied under paragraph (1)(D)(ii)—

(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) Reduced deductible

The dollar amount applied under paragraph (2)(B)—

(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1395w–102(b)(6) of this title for 2007; or

(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1395w–102(b)(6) of this title for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

(5) Waiver of de minimis premiums

The Secretary shall, under procedures established by the Secretary, permit a prescription drug plan or an MA–PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

(b) Premium subsidy amount

(1) In general

The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) Low-income benchmark premium amount defined

(A) In general

For purposes of this subsection, the term ''low-income benchmark premium amount'' means, with respect to a PDP region in which—

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1395w–21(a)(2)(A)(i) of this title offered in such region.

(B) Premium amounts described

The premium amounts described in this subparagraph are, in the case of—

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1395w–22(a)(6)(B)(ii)[1] of this title) and determined before the application of the monthly rebate computed under section 1395w–24(b)(1)(C)(i) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w–23(*o*) of this title for that plan and year involved.

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1395w–113(b) of this title.

(3) Access to 0 premium plan

In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) Administration of subsidy program

(1) In general

The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

(2) Use of capitated form of payment

The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) Facilitation of reassignments

Beginning not later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to a new prescription drug plan, provide the individual, within 30 days of such reassignment, with—

(1) information on formulary differences between the individual's former plan and the plan to which the individual is reassigned with respect to the individual's drug regimens; and

(2) a description of the individual's right to request a coverage determination, exception, or reconsideration under section 1395w–104(g) of this title, bring an appeal under section 1395w–104(h) of this title, or resolve a grievance under section 1395w–104(f) of this title.

[1] So in original. Section 1395w–22(a)(6) of this title does not contain a subpar. (B).

(e) Limited income newly eligible transition program

(1) In general

Beginning not later than January 1, 2024, the Secretary shall carry out a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

(2) LI NET eligible individual defined

For purposes of this subsection, the term ''LI NET eligible individual'' means a part D eligible individual who—

(A) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and

(B) has not yet enrolled in a prescription drug plan or an MA–PD plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

(3) Transitional coverage

For purposes of this subsection, the term ''transitional coverage'' means with respect to an LI NET eligible individual—

(A) immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA–PD plan takes effect with respect to such individual; and

(B) in the case of an LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title) or a recipient of supplemental security income benefits under subchapter XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or MA–PD plan) of covered part D drugs purchased by such individual during the period that begins on the date that is the later of—

(i) the date that such individual was first eligible for a low-income subsidy under this part; or

(ii) the date that is 36 months prior to the date such individual enrolls in a prescription drug plan or MA–PD plan,

and ends on the date that coverage under such plan takes effect.

(4) Program administration

(A) Point of contact

The Secretary shall, as determined appropriate by the Secretary, administer the program under this subsection through a contract with a single program administrator.

(B) Benefit design

The Secretary shall ensure that the transitional coverage provided to LI NET eligible individuals under this subsection—

(i) provides access to all covered part D drugs under an open formulary;

(ii) permits all pharmacies determined by the Secretary to be in good standing to process claims under the program;

(iii) is consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication; and

(iv) meets such other requirements as the Secretary may establish.

(5) Relationship to other provisions of this subchapter; waiver authority

(A) In general

The following provisions shall not apply with respect to the program under this subsection:

(i) Paragraphs (1) and (3)(B) of section 1395w–104(a) of this title (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(ii) Subparagraphs (A) and (B) of section 1395w–104(b)(3) of this title (relating to requirements on development and application of formularies; formulary development).

(iii) Paragraphs (1)(C) and (2) of section 1395w–104(c) of this title (relating to medication therapy management program).

(B) Waiver authority

The Secretary may waive such other requirements of subchapter XI and this subchapter as may be necessary to carry out the purposes of the program established under this subsection.

(6) Contracting authority

The authority vested in the Secretary by this subsection may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this subchapter.

(f) Relation to medicaid program

For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1396u–5 of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–14, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2107; amended Pub. L. 110–275, title I, §§ 114(a)(2), 116(a), 117(a), July 15, 2008, 122 Stat. 2506, 2507; Pub. L. 111–148, title III, §§ 3302(a), 3303(a), 3304(a), 3305, 3309, Mar. 23, 2010, 124 Stat. 468–470, 475; Pub. L. 111–152, title I, § 1102(c)(4), Mar. 30, 2010, 124 Stat. 1045; Pub. L. 116–260, div. CC, title I, § 118, Dec. 27, 2020, 134 Stat. 2950.)

AMENDMENTS

2020—Subsecs. (e), (f). Pub. L. 116–260 added subsec. (e) and redesignated former subsec. (e) as (f).

2010—Subsec. (a)(1)(D)(i). Pub. L. 111–148, § 3309, inserted ''or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1396b(m) of this title or under sec-

tion 1396u–2 of this title'' after ''1396a(q)(1)(B) of this title)''.

Subsec. (a)(3)(B)(vi). Pub. L. 111–148, § 3304(a), added cl. (vi).

Subsec. (a)(5). Pub. L. 111–148, § 3303(a), added par. (5).

Subsec. (b)(2)(B)(iii). Pub. L. 111–152 substituted ''and determined before the application of the monthly rebate computed under section 1395w–24(b)(1)(C)(i) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w–23(*o*) of this title for that plan and year involved'' for '', determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1395w–24(b)(1)(C) of this title or bonus payment under section 1395w–23(n) of this title''.

Pub. L. 111–148, § 3302(a), inserted '', determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1854(b)(1)(C) or bonus payment under section 1395w–23(n) of this title'' before period at end.

Subsecs. (d), (e). Pub. L. 111–148, § 3305, added subsec. (d) and redesignated former subsec. (d) as (e).

2008—Subsec. (a)(1)(A). Pub. L. 110–275, § 114(a)(2), substituted ''equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).'' for ''equal to—

''(i) 100 percent of the amount described in subsection (b)(1) of this section, but not to exceed the premium amount specified in subsection (b)(2)(B) of this section; plus

''(ii) 80 percent of any late enrollment penalties imposed under section 1395w–113(b) of this title for the first 60 months in which such penalties are imposed for that individual, and 100 percent of any such penalties for any subsequent month.''

Subsec. (a)(3)(B)(iv)(III). Pub. L. 110–275, § 117(a), added subcl. (III).

Subsec. (a)(3)(C)(i). Pub. L. 110–275, § 116(a)(1), inserted ''and except that support and maintenance furnished in kind shall not be counted as income'' after ''section 1396a(r)(2) of this title''.

Subsec. (a)(3)(D), (E)(i). Pub. L. 110–275, § 116(a)(2), (3), inserted ''subject to the life insurance policy exclusion provided under subparagraph (G)'' after ''program'' in introductory provisions.

Subsec. (a)(3)(G). Pub. L. 110–275, § 116(a)(4), added subpar. (G).

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3302(b), Mar. 23, 2010, 124 Stat. 468, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to premiums for months beginning on or after January 1, 2011.''

Amendment by section 3303(a) of Pub. L. 111–148 applicable to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011, see section 3303(c) of Pub. L. 111–148, set out as a note under section 1395w–101 of this title.

Pub. L. 111–148, title III, § 3304(b), Mar. 23, 2010, 124 Stat. 470, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2011.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 114(a)(2) of Pub. L. 110–275 applicable to subsidies for months beginning with Jan. 2009, see section 114(b) of Pub. L. 110–275, set out as a note under section 1395w–113 of this title.

Pub. L. 110–275, title I, § 116(b), July 15, 2008, 122 Stat. 2507, provided that: ''The amendments made by this section [amending this section] shall take effect with respect to applications filed on or after January 1, 2010.''

Pub. L. 110–275, title I, § 117(b), July 15, 2008, 122 Stat. 2507, provided that: ''The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [Pub. L. 108–173].''

GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS

Pub. L. 108–173, title I, § 107(e), Dec. 8, 2003, 117 Stat. 2171, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which drug utilization and access to covered part D drugs under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals but for the application of section 1860D–14(a)(3)(A)(iii) of such Act [42 U.S.C. 1395w–114(a)(3)(A)(iii)].

''(2) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under paragraph (1) that includes such recommendations for legislation as the Comptroller General determines are appropriate.''

§ 1395w–114a. Medicare coverage gap discount program

(a) Establishment

The Secretary shall establish a Medicare coverage gap discount program (in this section referred to as the ''program'') by not later than January 1, 2011. Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after March 23, 2010, in consultation with manufacturers, and allow for comment on such model agreement.

(b) Terms of agreement

(1) In general

(A) Agreement

An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.

(B) Provision of discounted prices at the point-of-sale

Except as provided in subsection (c)(1)(A)(iii), such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

(C) Timing of agreement

(i) Special rule for 2011

In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than not later than[1] 30 days after the date of the establishment of a model agreement under subsection (a).

(ii) 2012 and subsequent years

In order for an agreement with a manufacturer to be in effect under this section

[1] So in original. Second ''not later than'' probably should not appear.

with respect to plan year 2012 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

(2) Provision of appropriate data

Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) Compliance with requirements for administration of program

Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

(4) Length of agreement

(A) In general

An agreement under this section shall be effective for an initial period of not less than 18 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

(iv) Notice to third party

The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

(c) Duties described and special rule for supplemental benefits

(1) Duties described

The duties described in this subsection are the following:

(A) Administration of program

Administering the program, including—

(i) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

(ii) except as provided in clause (iii), the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

(iii) in the case where, during the period beginning on January 1, 2011, and ending on December 31, 2011, it is not practicable to provide such discounted prices at the point-of-sale (as described in clause (ii)), the establishment of procedures to provide such discounted prices as soon as practicable after the point-of-sale;

(iv) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

(I) the negotiated price of the applicable drug; and

(II) the discounted price of the applicable drug;

(v) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify;

(vi) the establishment of procedures to implement the special rule for supplemental benefits under paragraph (2); and

(vii) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

(B) Monitoring compliance

(i) In general

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

(ii) Notification

If a third party with a contract under subsection (d)(3) determines that the man-

ufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

(C) Collection of data from prescription drug plans and MA–PD plans

The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

(2) Special rule for supplemental benefits

For plan year 2011 and each subsequent plan year, in the case where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug.

(d) Administration

(1) In general

Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c)(1).

(2) Limitation

(A) In general

Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

(B) Exception

The limitation under subparagraph (A) shall not apply to the Secretary with respect to drugs dispensed during the period beginning on January 1, 2011, and ending on December 31, 2011, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to discounted prices during such period.

(3) Contract with third parties

The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

(4) Performance requirements

The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

(5) Implementation

The Secretary may implement the program under this section by program instruction or otherwise.

(6) Administration

Chapter 35 of title 44 shall not apply to the program under this section.

(e) Enforcement

(1) Audits

Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

(2) Civil money penalty

(A) In general

The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

(ii) 25 percent of such amount.

(B) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(f) Clarification regarding availability of other covered part D drugs

Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

(g) Definitions

In this section:

(1) Applicable beneficiary

The term ''applicable beneficiary'' means an individual who, on the date of dispensing a covered part D drug—

(A) is enrolled in a prescription drug plan or an MA–PD plan;

(B) is not enrolled in a qualified retiree prescription drug plan;

(C) is not entitled to an income-related subsidy under section 1395w–114(a) of this title; and

(D) who—

(i) has reached or exceeded the initial coverage limit under section 1395w–102(b)(3) of this title during the year; and

(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title.

(2) Applicable drug

The term ''applicable drug'' means, with respect to an applicable beneficiary, a covered part D drug—

(A) approved under a new drug application under section 355(b) of title 21 or, in the case of a biologic product, licensed under section 262 of this title (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 262); and

(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(iii) is provided through an exception or appeal.

(3) Applicable number of calendar days

The term ''applicable number of calendar days'' means—

(A) with respect to claims for reimbursement submitted electronically, 14 days; and

(B) with respect to claims for reimbursement submitted otherwise, 30 days.

(4) Discounted price

(A) In general

The term ''discounted price'' means 50 percent (or, with respect to a plan year after plan year 2018, 30 percent) of the negotiated price of the applicable drug of a manufacturer.

(B) Clarification

Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

(C) Special case for certain claims

In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the initial coverage limit under section 1395w–102(b)(3) of this title and below the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such initial coverage limit and below such annual out-of-pocket threshold.

(5) Manufacturer

The term ''manufacturer'' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Negotiated price

The term ''negotiated price'' has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (as in effect on March 23, 2010), except that such negotiated price shall not include any dispensing fee for the applicable drug.

(7) Qualified retiree prescription drug plan

The term ''qualified retiree prescription drug plan'' has the meaning given such term in section 1395w–132(a)(2) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–14A, as added Pub. L. 111–148, title III, § 3301(b), Mar. 23, 2010, 124 Stat. 462; amended Pub. L. 111–152, title I, § 1101(b)(2), Mar. 30, 2010, 124 Stat. 1037; Pub. L. 115–123, div. E, title XII, §§ 53113, 53116(b), Feb. 9, 2018, 132 Stat. 305, 307.)

AMENDMENTS

2018—Subsec. (g)(2)(A). Pub. L. 115–123, § 53113, inserted '', with respect to a plan year before 2019,'' after ''other than''.

Subsec. (g)(4)(A). Pub. L. 115–123, § 53116(b), inserted ''(or, with respect to a plan year after plan year 2018, 30 percent)'' after ''50 percent''.

2010—Subsec. (a). Pub. L. 111–152, § 1101(b)(2)(A), substituted ''January 1, 2011'' for ''July 1, 2010'' and ''180 days after March 23, 2010'' for ''April 1, 2010''.

Subsec. (b)(1)(C)(i). Pub. L. 111–152, § 1101(b)(2)(B)(i), which directed the amendment of subpar. (C) by striking out ''2010 and'' in the heading, was executed by striking ''2010 and'' before ''2011'' in cl. (i) heading to reflect the probable intent of Congress.

Pub. L. 111–152, § 1101(b)(2)(B)(ii), (iii), substituted ''January 1, 2011'' for ''July 1, 2010'' and ''not later than 30 days after the date of the establishment of a model agreement under subsection (a)'' for ''May 1, 2010''.

Subsec. (c)(1)(A)(iii). Pub. L. 111–152, § 1101(b)(2)(C)(i), substituted ''January 1, 2011, and ending on December 31, 2011'' for ''July 1, 2010, and ending on December 31, 2011''.

Subsec. (c)(2). Pub. L. 111–152, § 1101(b)(2)(C)(ii), substituted ''2011'' for ''2010''.

Subsec. (d)(2)(B). Pub. L. 111–152, § 1101(b)(2)(D), substituted ''January 1, 2011, and ending on December 31, 2011'' for ''July 1, 2010, and ending on December 31, 2010''.

Subsec. (g)(1). Pub. L. 111–152, § 1101(b)(2)(E)(i), substituted ''a covered part D drug'' for ''an applicable drug'' in introductory provisions.

Subsec. (g)(1)(C) to (E). Pub. L. 111–152, § 1101(b)(2)(E)(ii)–(iv), inserted ''and'' at end of subpar.

(C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: ''is not subject to a reduction in premium subsidy under section 1395r(i) of this title; and''.

§ 1395w–115. Subsidies for part D eligible individuals for qualified prescription drug coverage

(a) Subsidy payment

In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

(1) Direct subsidy

A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—

(A) the amount of the plan's standardized bid amount (as defined in section 1395w–113(a)(5) of this title), adjusted under subsection (c)(1), reduced by

(B) the base beneficiary premium (as computed under paragraph (2) of section 1395w–113(a) of this title and as adjusted under paragraph (1)(B) of such section).

(2) Subsidy through reinsurance

The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) Reinsurance payment amount

(1) In general

The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title.

(2) Allowable reinsurance costs

For purposes of this section, the term ''allowable reinsurance costs'' means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(3) Gross covered prescription drug costs

For purposes of this section, the term ''gross covered prescription drug costs'' means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) Coverage year defined

For purposes of this section, the term ''coverage year'' means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) Adjustments relating to bids

(1) Health status risk adjustment

(A) Establishment of risk adjustors

The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) Considerations

In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1395w–23(a)(3) of this title to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

(C) Data collection

In order to carry out this paragraph, the Secretary shall require—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary

and such other information as the Secretary determines necessary.

(D) Publication

At the time of publication of risk adjustment factors under section 1395w–23(b)(1)(B)(i)(II) of this title, the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) Geographic adjustment

(A) In general

Subject to subparagraph (B), for purposes of section 1395w–113(a)(1)(B)(iii) of this title, the Secretary shall establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1395w–113(a)(4) of this title) to take into account differences in prices for covered part D drugs among PDP regions.

(B) De minimis rule

If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) Budget neutral adjustment

Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

(d) Payment methods

(1) In general

Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

(2) Requirement for provision of information

(A) Requirement

Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) Restriction on use of information

Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) Source of payments

Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) Application of enrollee adjustment

The provisions of section 1395w–23(a)(2) of this title shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1395w–23(a) of this title.

(e) Portion of total payments to a sponsor or organization subject to risk (application of risk corridors)

(1) Computation of adjusted allowable risk corridor costs

(A) In general

For purposes of this subsection, the term ''adjusted allowable risk corridor costs'' means, for a plan for a coverage year (as defined in subsection (b)(4))—

(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1395w–114 of this title to the sponsor of the plan for the year.

(B) Allowable risk corridor costs

For purposes of this subsection, the term ''allowable risk corridor costs'' means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1395w–111(c)(2) of this title. In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1395w–114(a) of this title of the maximum amount of copayments permitted under such paragraphs.

(2) Adjustment of payment

(A) No adjustment if adjusted allowable risk corridor costs within risk corridor

If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

(B) Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor

(i) Costs between first and second threshold upper limits

If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) Costs above second threshold upper limits

If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) Conditions for application of higher percentage for 2006 and 2007

The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

(C) Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor

(i) Costs between first and second threshold lower limits

If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) Costs below second threshold lower limit

If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

(3) Establishment of risk corridors

(A) In general

For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) First threshold lower limit

The first threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) Second threshold lower limit

The second threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) First threshold upper limit

The first threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (i)(II).

(iv) Second threshold upper limit

The second threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (ii)(II).

(B) Target amount described

The target amount described in this paragraph is, with respect to a prescription drug plan or an MA–PD plan in a year, the total amount of payments paid to the PDP sponsor or MA–PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1395w–113(a)(5) of this title and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

(C) First and second threshold risk percentage defined

(i) First threshold risk percentage

Subject to clause (iii), for purposes of this section, the first threshold risk percentage is—

(I) for 2006 and 2007, and[1] 2.5 percent;

(II) for 2008 through 2011, 5 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

(ii) Second threshold risk percentage

Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

(I) for 2006 and 2007, 5 percent;

(II) for 2008 through 2011, 10 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

(iii) Reduction of risk percentage to ensure 2 plans in an area

Pursuant to section 1395w–111(b)(2)(E)(ii) of this title, a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

(4) Plans at risk for entire amount of supplemental prescription drug coverage

A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) No effect on monthly premium

No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) Disclosure of information

(1) In general

Each contract under this part and under part C shall provide that—

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) Restriction on use of information

Information disclosed or obtained pursuant to the provisions of this section may be used—

(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

(i) carrying out this section; and

(ii) conducting oversight, evaluation, and enforcement under this subchapter;

(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities; and

(C) by the Executive Director of the Medicare Payment Advisory Commission for purposes of monitoring, making recommendations for, and analysis of the program under this subchapter and by the Executive Director of the Medicaid and CHIP Payment and Access Commission for purposes of monitoring, making recommendations for, and analysis of the Medicaid program established under subchapter XIX and the Children's Health Insurance Program under subchapter XXI.

(3) Additional restrictions on disclosure of information

(A) In general

The Executive Directors described in paragraph (2)(C) shall not disclose any of the following information disclosed to such Executive Directors or obtained by such Executive Directors pursuant to such paragraph, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization:

(i) The specific amounts or the identity of the source of any rebates, discounts, price concessions, or other forms of direct or indirect remuneration under such prescription drug plan or such MA–PD plan.

(ii) Information submitted with the bid submitted under section 1395w–111(b) of this title by such PDP sponsor or under section 1395w–24(a) of this title by such MA organization.

(iii) In the case of such information from prescription drug event records, information in a form that would not be permitted under section 423.505(m) of title 42, Code of Federal Regulations, or any successor regulation, if released by the Centers for Medicare & Medicaid Services.

(B) Clarification

The restrictions on disclosures described in subparagraph (A) shall also apply to dis-

[1] So in original. The word ''and'' probably should not appear.

closures to individual Commissioners of the Medicare Payment Advisory Commission or of the Medicaid and CHIP Payment and Access Commission.

(g) Payment for fallback prescription drug plans

In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1395w–111(g)(4) of this title[2]), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1395w–111(g)(5) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–15, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2113; amended Pub. L. 111–148, title VI, § 6402(b)(1), Mar. 23, 2010, 124 Stat. 756; Pub. L. 116–260, div. CC, title I, § 112(a), Dec. 27, 2020, 134 Stat. 2946.)

REFERENCES IN TEXT

Section 1395w–111(g)(4) of this title, referred to in subsec. (g), was in the original ''section 1860D–3(c)(4)'', and was translated as reading ''section 1860D–11(g)(4)'', meaning section 1860D–11(g)(4) of the Social Security Act, to reflect the probable intent of Congress, because section 1860D–3, which is classified to section 1395w–103 of this title, does not contain a subsec. (c), and section 1395w–111(g)(4) of this title defines ''fallback prescription drug plan'' for purposes of this part.

AMENDMENTS

2020—Subsec. (f)(2)(C). Pub. L. 116–260, § 112(a)(1), added subpar. (C).

Subsec. (f)(3). Pub. L. 116–260, § 112(a)(2), added par. (3).

2010—Subsec. (f)(2). Pub. L. 111–148 substituted ''may be used—'' for ''may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.'' in introductory provisions and added subpars. (A) and (B).

§ 1395w–116. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund

(a) Establishment and operation of Account

(1) Establishment

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title an account to be known as the ''Medicare Prescription Drug Account'' (in this section referred to as the ''Account'').

(2) Funding

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, such Account as provided in this part.

(3) Separate from rest of Trust Fund

Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

[2] See References in Text note below.

(b) Payments from Account

(1) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including—

(A) payments under section 1395w–114 of this title (relating to low-income subsidy payments);

(B) payments under section 1395w–115 of this title (relating to subsidy payments and payments for fallback plans);

(C) payments to sponsors of qualified retiree prescription drug plans under section 1395w–132(a) of this title; and

(D) payments with respect to administrative expenses under this part in accordance with section 401(g) of this title.

(2) Transfers to Medicaid account for increased administrative costs

The Managing Trustee shall transfer from time to time from the Account to the Grants to States for Medicaid account amounts the Secretary certifies are attributable to increases in payment resulting from the application of section 1396u–5(b) of this title.

(3) Payments of premiums withheld

The Managing Trustee shall make payment to the PDP sponsor or MA organization involved of the premiums (and the portion of late enrollment penalties) that are collected in the manner described in section 1395w–24(d)(2)(A) of this title and that are payable under a prescription drug plan or MA–PD plan offered by such sponsor or organization.

(4) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(c) Deposits into Account

(1) Low-income transfer

Amounts paid under section 1396u–5(c) of this title (and any amounts collected or offset under paragraph (1)(C) of such section) are deposited into the Account.

(2) Amounts withheld

Pursuant to sections 1395w–113(c) and 1395w–24(d) of this title (as applied under this part), amounts that are withheld (and allocated) to the Account are deposited into the Account.

(3) Appropriations to cover Government contributions

There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Account, an amount equivalent to the amount of payments made from the Account under subsection (b) plus such amounts as the Managing Trustee certifies is necessary to maintain an appropriate contingency margin, reduced by the amounts deposited under paragraph (1) or subsection (a)(2).

(4) Initial funding and reserve

In order to assure prompt payment of benefits provided under this part and the adminis-

trative expenses thereunder during the early months of the program established by this part and to provide an initial contingency reserve, there are authorized to be appropriated to the Account, out of any moneys in the Treasury not otherwise appropriated, such amount as the Secretary certifies are required, but not to exceed 10 percent of the estimated total expenditures from such Account in 2006.

(5) Transfer of any remaining balance from Transitional Assistance Account

Any balance in the Transitional Assistance Account that is transferred under section 1395w–141(k)(5) of this title shall be deposited into the Account.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–16, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2120.)

SUBPART 3—APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND TREATMENT OF EMPLOYER-SPONSORED PROGRAMS AND OTHER PRESCRIPTION DRUG PLANS

§ 1395w–131. Application to Medicare Advantage program and related managed care programs

(a) Special rules relating to offering of qualified prescription drug coverage

(1) In general

An MA organization on and after January 1, 2006—

(A) may not offer an MA plan described in section 1395w–21(a)(2)(A) of this title in an area unless either that plan (or another MA plan offered by the organization in that same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

(B) may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee—

(i) under an MSA plan; or

(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

(2) Qualifying coverage

For purposes of paragraph (1)(A), the term ''required coverage'' means with respect to an MA–PD plan—

(A) basic prescription drug coverage; or

(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title).

(b) Application of default enrollment rules

(1) Seamless continuation

In applying section 1395w–21(c)(3)(A)(ii) of this title, an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA–PD plan unless such health benefits plan provides any prescription drug coverage.

(2) MA continuation

In applying section 1395w–21(c)(3)(B) of this title, an individual who is enrolled in an MA plan shall not be considered to have been deemed to make an election into an MA–PD plan unless—

(A) for purposes of the election as of January 1, 2006, the MA plan provided as of December 31, 2005, any prescription drug coverage; or

(B) for periods after January 1, 2006, such MA plan is an MA–PD plan.

(3) Discontinuance of MA–PD election during first year of eligibility

In applying the second sentence of section 1395w–21(e)(4) of this title in the case of an individual who is electing to discontinue enrollment in an MA–PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D at the time of the election of coverage under the original medicare fee-for-service program.

(4) Rules regarding enrollees in MA plans not providing qualified prescription drug coverage

In the case of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage—

(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA–PD plan; and

(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1395ss(s)(3) of this title for purposes of applying such section.

The information disclosed under section 1395w–22(c)(1) of this title for individuals who are enrolled in such an MA plan shall include information regarding such rules.

(c) Application of part D rules for prescription drug coverage

With respect to the offering of qualified prescription drug coverage by an MA organization under this part on and after January 1, 2006—

(1) In general

Except as otherwise provided, the provisions of this part shall apply under part C with respect to prescription drug coverage provided under MA–PD plans in lieu of the other provisions of part C that would apply to such coverage under such plans.

(2) Waiver

The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan

under part C or as may be necessary in order to improve coordination of this part with the benefits under this part.

(3) Treatment of MA owned and operated pharmacies

The Secretary may waive the requirement of section 1395w–104(b)(1)(C) of this title in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

(d) Special rules for private fee-for-service plans that offer prescription drug coverage

With respect to an MA plan described in section 1395w–21(a)(2)(C) of this title that offers qualified prescription drug coverage, on and after January 1, 2006, the following rules apply:

(1) Requirements regarding negotiated prices

Subsections (a)(1) and (d)(1) of section 1395w–102 of this title and section 1395w–104(b)(2)(A) of this title shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

(2) Modification of pharmacy access standard and disclosure requirement

If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1395w–104 of this title shall not apply to the plan.

(3) Drug utilization management program and medication therapy management program not required

The requirements of subparagraphs (A) and (C) of section 1395w–104(c)(1) of this title shall not apply to the plan.

(4) Application of reinsurance

The Secretary shall determine the amount of reinsurance payments under section 1395w–115(b) of this title using a methodology that—

(A) bases such amount on the Secretary's estimate of the amount of such payments that would be payable if the plan were an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title and the previous provisions of this subsection did not apply; and

(B) takes into account the average reinsurance payments made under section 1395w–115(b) of this title for populations of similar risk under MA–PD plans described in such section.

(5) Exemption from risk corridor provisions

The provisions of section 1395w–115(e) of this title shall not apply.

(6) Exemption from negotiations

Subsections (d) and (e)(2)(C) of section 1395w–111 of this title shall not apply and the provisions of section 1395w–24(a)(5)(B) of this title prohibiting the review, approval, or disapproval of amounts described in such section shall apply to the proposed bid and terms and conditions described in section 1395w–111(d) of this title.

(7) Treatment of incurred costs without regard to formulary

The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan's formulary under section 1395w–102(b)(4)(B)(i) of this title shall not apply insofar as the plan does not utilize a formulary.

(e) Application to reasonable cost reimbursement contractors

(1) In general

Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1395mm(h) of this title and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in the same manner as such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1395–21(a)(2)(A)(i) of this title and coverage under such a contract that so provides qualified prescription drug coverage shall be deemed to be an MA–PD local plan.

(2) Limitation on enrollment

In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

(3) Bids not included in determining national average monthly bid amount

The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part.

(f) Application to PACE

(1) In general

Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1395eee of this title that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1395w–21(a)(2)(A)(ii) of this title and a PACE program that so provides such coverage may be deemed to be an MA–PD local plan.

(2) Limitation on enrollment

In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

(3) Bids not included in determining standardized bid amount

The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–21, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2122.)

§ 1395w–132. Special rules for employer-sponsored programs

(a) Subsidy payment

(1) In general

The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount specified in paragraph (3) for each qualified covered retiree under the plan (as defined in paragraph (4)). This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(2) Qualified retiree prescription drug plan defined

For purposes of this subsection, the term ''qualified retiree prescription drug plan'' means employment-based retiree health coverage (as defined in subsection (c)(1)) if, with respect to a part D eligible individual who is a participant or beneficiary under such coverage, the following requirements are met:

(A) Attestation of actuarial equivalence to standard coverage

The sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require, with an attestation that the actuarial value of prescription drug coverage under the plan (as determined using the processes and methods described in section 1395w–111(c) of this title) is at least equal to the actuarial value of standard prescription drug coverage, not taking into account the value of any discount or coverage provided during the gap in prescription drug coverage that occurs between the initial coverage limit under section 1395w–102(b)(3) of this title during the year and the out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title.

(B) Audits

The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and afford the Secretary access to) such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made under this section. The provisions of section 1395w–102(d)(3) of this title shall apply to such information under this section (including such actuarial value and attestation) in a manner similar to the manner in which they apply to financial records of PDP sponsors and MA organizations.

(C) Provision of disclosure regarding prescription drug coverage

The sponsor of the plan shall provide for disclosure of information regarding prescription drug coverage in accordance with section 1395w–113(b)(6)(B) of this title.

(3) Employer and union special subsidy amounts

(A) In general

For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree's gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(ii)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

(B) Cost threshold and cost limit applicable

(i) In general

Subject to clause (ii)—

(I) the cost threshold under this subparagraph is equal to $250 for plan years that end in 2006; and

(II) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

(ii) Indexing

The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1395w–102(b) of this title.

(C) Definitions

For purposes of this paragraph:

(i) Allowable retiree costs

The term ''allowable retiree costs'' means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

(ii) Gross covered retiree plan-related prescription drug costs

For purposes of this section, the term ''gross covered retiree plan-related pre-

scription drug costs'' means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

(iii) Coverage year

The term ''coverage year'' has the meaning given such term in section 1395w–115(b)(4) of this title.

(4) Qualifying covered retiree defined

For purposes of this subsection, the term ''qualifying covered retiree'' means a part D eligible individual who is not enrolled in a prescription drug plan or an MA–PD plan but is covered under a qualified retiree prescription drug plan.

(5) Payment methods, including provision of necessary information

The provisions of section 1395w–115(d) of this title (including paragraph (2), relating to requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1395w–115(b) of this title.

(6) Construction

Nothing in this subsection shall be construed as—

(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA–PD plan;

(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of such an individual;

(C) preventing such employment-based retiree health coverage from providing coverage—

(i) that is better than standard prescription drug coverage to retirees who are covered under a qualified retiree prescription drug plan; or

(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA–PD plan; or

(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

(b) Application of MA waiver authority

The provisions of section 1395w–27(i) of this title shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

(c) Definitions

For purposes of this section:

(1) Employment-based retiree health coverage

The term ''employment-based retiree health coverage'' means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

(2) Sponsor

The term ''sponsor'' means a plan sponsor, as defined in section 1002(16)(B) of title 29, in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect to which the employer is the primary source of financing, such term means such employer.

(3) Group health plan

The term ''group health plan'' includes such a plan as defined in section 1167(1) of title 29 and also includes the following:

(A) Federal and State governmental plans

Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5.

(B) Collectively bargained plans

Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

(C) Church plans

Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of the Internal Revenue Code of 1986.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–22, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2125; amended Pub. L. 111–152, title I, §1101(b)(4), Mar. 30, 2010, 124 Stat. 1039.)

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (c)(3)(C), is classified generally to Title 26, Internal Revenue Code.

AMENDMENTS

2010—Subsec. (a)(2)(A). Pub. L. 111–152 inserted before period at end '', not taking into account the value of any discount or coverage provided during the gap in prescription drug coverage that occurs between the ini-

tial coverage limit under section 1395w–102(b)(3) of this title during the year and the out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title''.

STUDY ON EMPLOYMENT-BASED RETIREE HEALTH COVERAGE

Pub. L. 108–173, title I, § 111, Dec. 8, 2003, 117 Stat. 2174, provided that:

''(a) STUDY.—The Comptroller General of the United States shall conduct an initial and final study under this subsection [probably should be this section] to examine trends in employment-based retiree health coverage (as defined in [sic] 1860D–22(c)(1) of the Social Security Act [42 U.S.C. 1395w–132(c)(1)], as added by section 101), including coverage under the Federal Employees Health Benefits Program (FEHBP), and the options and incentives available under this Act [see Tables for classification] which may have an effect on the voluntary provision of such coverage.

''(b) CONTENT OF INITIAL STUDY.—The initial study under this section shall consider the following:

''(1) Trends in employment-based retiree health coverage prior to the date of the enactment of this Act [Dec. 8, 2003].

''(2) The opinions of sponsors of employment-based retiree health coverage concerning which of the options available under this Act [see Tables for classification] they are most likely to utilize for the provision of health coverage to their medicare-eligible retirees, including an assessment of the administrative burdens associated with the available options.

''(3) The likelihood of sponsors of employment-based retiree health coverage to maintain or adjust their levels of retiree health benefits beyond coordination with medicare, including for prescription drug coverage, provided to medicare-eligible retirees after the date of the enactment of this Act.

''(4) The factors that sponsors of employment-based retiree health coverage expect to consider in making decisions about any changes they may make in the health coverage provided to medicare-eligible retirees.

''(5) Whether the prescription drug plan options available, or the health plan options available under the Medicare Advantage program, are likely to cause employers and other entities that did not provide health coverage to retirees prior to the date of the enactment of this Act to provide supplemental coverage or contributions toward premium expenses for medicare-eligible retirees who may enroll in such options in the future.

''(c) CONTENTS OF FINAL STUDY.—The final study under this section shall consider the following:

''(1) Changes in the trends in employment-based retiree health coverage since the completion of the initial study by the Comptroller General.

''(2) Factors contributing to any changes in coverage levels.

''(3) The number and characteristics of sponsors of employment-based retiree health coverage who receive the special subsidy payments under section 1860D–22 of the Social Security Act [42 U.S.C. 1395w–132], as added by section 101, for the provision of prescription drug coverage to their medicare-eligible retirees that is the same or greater actuarial value as the prescription drug coverage available to other medicare beneficiaries without employment-based retiree health coverage.

''(4) The extent to which sponsors of employment-based retiree health coverage provide supplemental health coverage or contribute to the premiums for medicare-eligible retirees who enroll in a prescription drug plan or an MA–PD plan.

''(5) Other coverage options, including tax-preferred retirement or health savings accounts, consumer-directed health plans, or other vehicles that sponsors of employment-based retiree health coverage believe would assist retirees with their future health care needs and their willingness to sponsor such alternative plan designs.

''(6) The extent to which employers or other entities that did not provide employment-based retiree health coverage prior to the date of the enactment of this Act [Dec. 8, 2003] provided some form of coverage or financial assistance for retiree health care needs after the date of the enactment of this Act.

''(7) Recommendations by employers, benefits experts, academics, and others on ways that the voluntary provision of employment-based retiree health coverage may be improved and expanded.

''(d) REPORTS.—The Comptroller General shall submit a report to Congress on—

''(1) the initial study under subsection (b) not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003]; and

''(2) the final study under subsection (c) not later than January 1, 2007.

''(e) CONSULTATION.—The Comptroller General shall consult with sponsors of employment-based retiree health coverage, benefits experts, human resources professionals, employee benefits consultants, and academics with experience in health benefits and survey research in the development and design of the initial and final studies under this section.''

§ 1395w–133. State Pharmaceutical Assistance Programs

(a) Requirements for benefit coordination

(1) In general

Before July 1, 2005, the Secretary shall establish consistent with this section requirements for prescription drug plans to ensure the effective coordination between a part D plan (as defined in paragraph (5)) and a State Pharmaceutical Assistance Program (as defined in subsection (b)) with respect to—

(A) payment of premiums and coverage; and

(B) payment for supplemental prescription drug benefits,

for part D eligible individuals enrolled under both types of plans.

(2) Coordination elements

The requirements under paragraph (1) shall include requirements relating to coordination of each of the following:

(A) Enrollment file sharing.

(B) The processing of claims, including electronic processing.

(C) Claims payment.

(D) Claims reconciliation reports.

(E) Application of the protection against high out-of-pocket expenditures under section 1395w–102(b)(4) of this title.

(F) Other administrative processes specified by the Secretary.

Such requirements shall be consistent with applicable law to safeguard the privacy of any individually identifiable beneficiary information.

(3) Use of lump sum per capita method

Such requirements shall include a method for the application by a part D plan of specified funding amounts from a State Pharmaceutical Assistance Program for enrolled individuals for supplemental prescription drug benefits.

(4) Consultation

In establishing requirements under this subsection, the Secretary shall consult with State

Pharmaceutical Assistance Programs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of part D eligible individuals, the data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

(5) Part D plan defined

For purposes of this section and section 1395w–134 of this title, the term ''part D plan'' means a prescription drug plan and an MA–PD plan.

(b) State Pharmaceutical Assistance Program

For purposes of this part, the term ''State Pharmaceutical Assistance Program'' means a State program—

(1) which provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals;

(2) which, in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled; and

(3) which satisfies the requirements of subsections (a) and (c).

(c) Relation to other provisions

(1) Medicare as primary payor

The requirements of this section shall not change or affect the primary payor status of a part D plan.

(2) Use of a single card

A card that is issued under section 1395w–104(b)(2)(A) of this title for use under a part D plan may also be used in connection with coverage of benefits provided under a State Pharmaceutical Assistance Program and, in such case, may contain an emblem or symbol indicating such connection.

(3) Other provisions

The provisions of section 1395w–134(c) of this title shall apply to the requirements under this section.

(4) Special treatment under out-of-pocket rule

In applying section 1395w–102(b)(4)(C)(ii) of this title, expenses incurred under a State Pharmaceutical Assistance Program may be counted toward the annual out-of-pocket threshold.

(5) Construction

Nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide financial assistance with respect to any part D plan.

(d) Facilitation of transition and coordination with State Pharmaceutical Assistance Programs

(1) Transitional grant program

The Secretary shall provide payments to State Pharmaceutical Assistance Programs with an application approved under this subsection.

(2) Use of funds

Payments under this section may be used by a Program for any of the following:

(A) Educating part D eligible individuals enrolled in the Program about the prescription drug coverage available through part D plans under this part.

(B) Providing technical assistance, phone support, and counseling for such enrollees to facilitate selection and enrollment in such plans.

(C) Other activities designed to promote the effective coordination of enrollment, coverage, and payment between such Program and such plans.

(3) Allocation of funds

Of the amount appropriated to carry out this subsection for a fiscal year, the Secretary shall allocate payments among Programs that have applications approved under paragraph (4) for such fiscal year in proportion to the number of enrollees enrolled in each such Program as of October 1, 2003.

(4) Application

No payments may be made under this subsection except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary.

(5) Funding

Out of any funds in the Treasury not otherwise appropriated, there are appropriated for each of fiscal years 2005 and 2006, $62,500,000 to carry out this subsection.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–23, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2128.)

§ 1395w–134. Coordination requirements for plans providing prescription drug coverage

(a) Application of benefit coordination requirements to additional plans

(1) In general

The Secretary shall apply the coordination requirements established under section 1395w–133(a) of this title to Rx plans described in subsection (b) in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

(2) Application to treatment of certain out-of-pocket expenditures

To the extent specified by the Secretary, the requirements referred to in paragraph (1) shall apply to procedures established under section 1395w–102(b)(4)(D) of this title.

(3) User fees

(A) In general

The Secretary may impose user fees for the transmittal of information necessary for benefit coordination under section 1395w–102(b)(4)(D) of this title in a manner similar to the manner in which user fees are imposed under section 1395u(h)(3)(B) of this title, except that the Secretary may retain a portion of such fees to defray the Secretary's costs in carrying out procedures under section 1395w–102(b)(4)(D) of this title.

(B) Application

A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

(b) Rx Plan

An Rx plan described in this subsection is any of the following:

(1) Medicaid programs

A State plan under subchapter XIX, including such a plan operating under a waiver under section 1315 of this title, if it meets the requirements of section 1395w–133(b)(2) of this title.

(2) Group health plans

An employer group health plan.

(3) FEHBP

The Federal employees health benefits plan under chapter 89 of title 5.

(4) Military coverage (including TRICARE)

Coverage under chapter 55 of title 10.

(5) Other prescription drug coverage

Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of part D eligible individuals as the Secretary may specify.

(c) Relation to other provisions

(1) Use of cost management tools

The requirements of this section shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation.

(2) No affect[1] on treatment of certain out-of-pocket expenditures

The requirements of this section shall not affect the application of the procedures established under section 1395w–102(b)(4)(D) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–24, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2130.)

SUBPART 4—MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

§ 1395w–141. Medicare prescription drug discount card and transitional assistance program

(a) Establishment of program

(1) In general

The Secretary shall establish a program under this section—

(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

(2) Period of operation

(A) Implementation deadline

The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after December 8, 2003.

(B) Expediting implementation

The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

(C) Termination and transition

(i) In general

Subject to clause (ii)—

(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

(ii) Transition

In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

(II) no annual enrollment fee shall be applicable during the transition period;

(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

(iii) Transition period

The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who—

(I) is enrolled in a prescription drug plan or an MA–PD plan before the last date of the initial enrollment period under section 1395w–101(b)(2)(A) of this title, on the effective date of the individual's coverage under such part; or

(II) is not so enrolled, on the last day of such initial period.

(3) Voluntary nature of program

Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

[1] So in original. Probably should be ''effect''.

(4) Glossary and definitions of terms

For purposes of this section:

(A) Covered discount card drug

The term ''covered discount card drug'' has the meaning given the term ''covered part D drug'' in section 1395w–102(e) of this title.

(B) Discount card eligible individual

The term ''discount card eligible individual'' is defined in subsection (b)(1)(A).

(C) Endorsed discount card program; endorsed program

The terms ''endorsed discount card program'' and ''endorsed program'' mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

(D) Negotiated price

Negotiated prices are described in subsection (e)(1)(A)(ii).

(E) Prescription drug card sponsor; sponsor

The terms ''prescription drug card sponsor'' and ''sponsor'' are defined in subsection (h)(1)(A).

(F) State

The term ''State'' has the meaning given such term for purposes of subchapter XIX.

(G) Transitional assistance eligible individual

The term ''transitional assistance eligible individual'' is defined in subsection (b)(2).

(b) Eligibility for discount card and for transitional assistance

For purposes of this section:

(1) Discount card eligible individual

(A) In general

The term ''discount card eligible individual'' means an individual who—

(i) is entitled to benefits, or enrolled, under part A or enrolled under part B; and

(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

(B) Individual described

An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under subchapter XIX (or under a waiver under section 1315 of this title of the requirements of such subchapter) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1396d(a)(12) of this title.

(2) Transitional assistance eligible individual

(A) In general

Subject to subparagraph (B), the term ''transitional assistance eligible individual'' means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(B) Exclusion of individuals with certain prescription drug coverage

Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

(i) A group health plan or health insurance coverage (as such terms are defined in section 300gg–91 of this title), other than coverage under a plan under part C and other than coverage consisting only of excepted benefits (as defined in such section).

(ii) Chapter 55 of title 10 (relating to medical and dental care for members of the uniformed services).

(iii) A plan under chapter 89 of title 5 (relating to the Federal employees' health benefits program).

(3) Special transitional assistance eligible individual

The term ''special transitional assistance eligible individual'' means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(4) Treatment of medicaid medically needy

For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1396a(a)(10)(C) of this title as discount card eligible individuals and as transitional assistance eligible individuals.

(c) Enrollment and enrollment fees

(1) Enrollment process

The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

(A) Continuous open enrollment

Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

(i) that serves residents of the State; and

(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

(B) Use of standard enrollment form

An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent

provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

(C) Enrollment only in one program

(i) In general

Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

(ii) Change in endorsed program permitted for 2005

The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1395w–21(e)(3) of this title during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

(iii) Additional exceptions

The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1395w–21(e)(4) of this title). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

(D) Disenrollment

(i) Voluntary

An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

(ii) Involuntary

An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

(E) Application to certain enrollees

In the case of a discount card eligible individual who is enrolled in a plan described in section 1395w–21(a)(2)(A) of this title or under a reasonable cost reimbursement contract under section 1395mm(h) of this title that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

(2) Enrollment fees

(A) In general

Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

(B) Amount

No annual enrollment fee charged under subparagraph (A) may exceed $30.

(C) Uniform enrollment fee

A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

(D) Collection

The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

(E) Payment of fee for transitional assistance eligible individuals

Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

(F) Optional payment of fee by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI.

(G) Rules in case of changes in program enrollment during a year

The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible indi-

vidual who changes the endorsed program in which the individual is enrolled during a year.

(3) Issuance of discount card

Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

(4) Period of access

In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

(d) Provision of information on enrollment and program features

(1) Secretarial responsibilities

(A) In general

The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding—

(i) enrollment in endorsed discount card programs; and

(ii) the features of the program under this section, including the availability of transitional assistance.

(B) Promotion of informed choice

In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and

(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

(C) Special rule for initial enrollment date under the program

To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

(D) Use of medicare toll-free number

The Secretary shall provide through the toll-free telephone number 1–800–MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

(2) Prescription drug card sponsor responsibilities

(A) In general

Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

(B) Response to enrollee questions

Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

(C) Information on balance of transitional assistance available at point-of-sale

Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

(3) Public disclosure of pharmaceutical prices for equivalent drugs

(A) In general

A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(B) Timing of notice

(i) In general

Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(ii) Waiver

The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

(e) Discount card features

(1) Savings to enrollees through negotiated prices

(A) Access to negotiated prices

(i) In general

Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

(ii) Negotiated prices

For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

(B) Ensuring pharmacy access

Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(C) Prohibition on charges for required services

(i) In general

Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

(ii) Construction

Nothing in clause (i) shall be construed to prevent—

(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

(D) Inapplicability of medicaid best price rules

The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396r–8(c)(1)(C) of this title.

(2) Reduction of medication errors and adverse drug interactions

Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

(f) Eligibility procedures for endorsed programs and transitional assistance

(1) Determinations

(A) Procedures

The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

(B) Income and family size determinations

For purposes of this section, the Secretary shall define the terms ''income'' and ''family size'' and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

(2) Use of self-certification for transitional assistance

(A) In general

Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

(B) Treatment of self-certification

The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that

the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

(3) Verification

(A) In general

The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

(B) Information described

The information described in this subparagraph is as follows:

(i) Medicaid-related information

Information on eligibility under subchapter XIX and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

(ii) Social security information

Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

(iii) Information from Secretary of the Treasury

Financial information made available to the Secretary under section 6103(*l*)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

(C) Verification in cases of medicaid enrollees

(i) In general

Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under subchapter XIX (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI–1s)).

(ii) Availability of information for verification purposes

As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under subchapter XIX, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such subchapter in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

(4) Reconsideration

(A) In general

The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

(B) Contract authority

The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

(C) Communication of results

Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

(g) Transitional assistance

(1) Provision of transitional assistance

An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

(2) Limitation on dollar amount

(A) In general

Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

(i) for costs incurred during 2004, is $600; or

(ii) for costs incurred during 2005, is—

(I) $600, plus

(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

(B) Proration

(i) In general

In the case of an individual not described in clause (ii) with respect to a year, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

(ii) Individual described

An individual described in this clause is a transitional assistance eligible individual who—

(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

(C) Accounting for available balances in cases of changes in program enrollment

In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

(D) Limitation on use of funds

Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

(E) No rollover permitted in case of voluntary disenrollment

Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

(3) Payment

The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

(4) Coverage of coinsurance

(A) Waiver permitted by pharmacy

Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1320a–7b(b)(3)(G) of this title.

(B) Optional payment of coinsurance by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI.

(iii) Not treated as medicare cost-sharing

Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this subchapter for purposes of section 1396d(p)(3)(B) of this title.

(C) Treatment of coinsurance

The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

(5) Ensuring access to transitional assistance for qualified residents of long-term care facilities and American Indians

(A) Residents of long-term care facilities

The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

(B) American Indians

The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

(6) No impact on benefits under other programs

The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(7) Disregard for purposes of part C

Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1395w–24(f) of this title.

(h) Qualification of prescription drug card sponsors and endorsement of discount card programs; beneficiary protections

(1) Prescription drug card sponsor and qualifications

(A) Prescription drug card sponsor and sponsor defined

For purposes of this section, the terms ''prescription drug card sponsor'' and ''spon-

sor'' mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

(i) a pharmaceutical benefit management company;

(ii) a wholesale or retail pharmacy delivery system;

(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1395ss of this title);

(iv) an organization offering a plan under part C; or

(v) any combination of the entities described in clauses (i) through (iv).

(B) Administrative qualifications

Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

(C) Accounting for transitional assistance

The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

(2) Applications for program endorsement

(A) Submission

Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

(B) Approval; compliance with applicable requirements

The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless—

(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

(C) Termination of endorsement and contracts

An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

(D) Ensuring choice of programs

(i) In general

The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

(ii) Limitation on number

The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

(3) Service area encompassing entire States

Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

(4) Savings to medicare beneficiaries

Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

(5) Grievance mechanism

Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1395w–22(f) of this title.

(6) Confidentiality of enrollee records

(A) In general

For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of subchapter XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).[1]

(B) Waiver authority

In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

(7) Limitation on provision and marketing of products and services

The sponsor of an endorsed discount card program—

[1] See References in Text note below.

(A) may provide under the program—

(i) a product or service only if the product or service is directly related to a covered discount card drug; or

(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

(8) Additional protections

Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

(9) Special rules for certain organizations

(A) In general

In the case of an organization that is offering a plan under part C or enrollment under a reasonable cost reimbursement contract under section 1395mm(h) of this title that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1395w–21(a)(2)(A) of this title that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

(B) Special rules

The special rules under this subparagraph are as follows:

(i) Limitation on enrollment

The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

(ii) Pharmacy access

Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

(iii) Sponsor requirements

The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C or section 1395mm of this title (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

(i) Disclosure and oversight

(1) Disclosure

Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1396r–8(b)(3)(D) of this title shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

(2) Oversight; audit and inspection authority

The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

(3) Sanctions for abusive practices

The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1320a–7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(j) Treatment of territories

(1) In general

The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

(2) Transitional assistance

(A) In general

In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

(B) Plan

The plan described in this subparagraph is a plan that—

(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A or enrolled under part B, who reside in the State, and who have income below 135 percent of the poverty line; and

(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

(C) Allotment limit

The amount described in this subparagraph for a State is equal to $35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

(i) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary as of July 1, 2003), to

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) Continued availability of funds

Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1396u–5(e) of this title.

(k) Funding

(1) Establishment of Transitional Assistance Account

(A) In general

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title an account to be known as the ''Transitional Assistance Account'' (in this subsection referred to as the ''Account'').

(B) Funds

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

(C) Separate from rest of Trust Fund

Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(2) Payments from account

(A) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

(B) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(3) Appropriations to cover benefits

There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) For administrative expenses

There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary's responsibilities under this section.

(5) Transfer of any remaining balance to Medicare Prescription Drug Account

Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1395w–116 of this title.

(6) Construction

Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–31, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2131.)

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (f)(3)(B)(iii), is classified generally to Title 26, Internal Revenue Code.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(6)(A), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

RULES FOR IMPLEMENTATION

Pub. L. 108–173, title I, §105(c), Dec. 8, 2003, 117 Stat. 2166, provided that: ''The following rules shall apply to the medicare prescription drug discount card and transitional assistance program under section 1860D–31 of the Social Security Act [42 U.S.C. 1395w–141], as added by section 101(a):

''(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D–31 [42 U.S.C. 1395w–141(a)(2)(B)]—

''(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

''(B) chapter 35 of title 44, United States Code, shall not apply; and

''(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

''(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w–27(c)(5)) shall apply with respect to section 1860D–31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act [42 U.S.C. 1395w–21 et seq.].

''(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

''(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D–31 of the Social Security Act.

''(B) In the case of any order issued to enjoin any provision of section 1860D–31 of the Social Security Act (or of [sic] any provision of this section [amending sections 1395r, 1395t, and 1396r–8 of this title and sections 6103 and 7213 of Title 26, Internal Revenue Code]), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.''

SUBPART 5—DEFINITIONS AND MISCELLANEOUS PROVISIONS

§ 1395w–151. Definitions; treatment of references to provisions in part C

(a) Definitions

For purposes of this part:

(1) Basic prescription drug coverage

The term ''basic prescription drug coverage'' is defined in section 1395w–102(a)(3) of this title.

(2) Covered part D drug

The term ''covered part D drug'' is defined in section 1395w–102(e) of this title.

(3) Creditable prescription drug coverage

The term ''creditable prescription drug coverage'' has the meaning given such term in section 1395w–113(b)(4) of this title.

(4) Part D eligible individual

The term ''part D eligible individual'' has the meaning given such term in section 1395w–101(a)(3)(A) of this title.[1]

(5) Fallback prescription drug plan

The term ''fallback prescription drug plan'' has the meaning given such term in section 1395w–111(g)(4) of this title.

(6) Initial coverage limit

The term ''initial coverage limit'' means such limit as established under section 1395w–102(b)(3) of this title, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

(7) Insurance risk

The term ''insurance risk'' means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA plan

The term ''MA plan'' has the meaning given such term in section 1395w–101(a)(3)(B) of this title.[1]

(9) MA–PD plan

The term ''MA–PD plan'' has the meaning given such term in section 1395w–101(a)(3)(C) of this title.[1]

(10) Medicare Prescription Drug Account

The term ''Medicare Prescription Drug Account'' means the Account created under section 1395w–116(a) of this title.

(11) PDP approved bid

The term ''PDP approved bid'' has the meaning given such term in section 1395w–113(a)(6) of this title.

(12) PDP region

The term ''PDP region'' means such a region as provided under section 1395w–111(a)(2) of this title.

(13) PDP sponsor

The term ''PDP sponsor'' means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(14) Prescription drug plan

The term ''prescription drug plan'' means prescription drug coverage that is offered—

(A) under a policy, contract, or plan that has been approved under section 1395w–111(e) of this title; and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1395w–112(b) of this title.

(15) Qualified prescription drug coverage

The term ''qualified prescription drug coverage'' is defined in section 1395w–102(a)(1) of this title.

(16) Standard prescription drug coverage

The term ''standard prescription drug coverage'' is defined in section 1395w–102(b) of this title.

(17) State Pharmaceutical Assistance Program

The term ''State Pharmaceutical Assistance Program'' has the meaning given such term in section 1395w–133(b) of this title.

(18) Subsidy eligible individual

The term ''subsidy eligible individual'' has the meaning given such term in section 1395w–114(a)(3)(A) of this title.

(b) Application of part C provisions under this part

For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

(1) any reference to an MA plan included a reference to a prescription drug plan;

[1] See References in Text note below.

(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1395w–27 of this title included a reference to a contract under section 1395w–112(b) of this title;

(4) any reference to part C included a reference to this part; and

(5) any reference to an election period under section 1395w–21 of this title were a reference to an enrollment period under section 1395w–101 of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–41, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2148.)

REFERENCES IN TEXT

Section 1395w–101(a)(3) of this title, referred to in subsec. (a)(4), (8), (9), was in the original ''section 1860D–1(a)(4)'', and was translated as meaning section 1860D–1(a)(3) of act Aug. 14, 1935, which is classified to section 1395w–101(a)(3) of this title, to reflect the probable intent of Congress, because section 1395w–101(a) of this title does not contain a par. (4) and par. (3) defines terms for purposes of this part.

§ 1395w–152. Miscellaneous provisions

(a) Access to coverage in territories

The Secretary may waive such requirements of this part, including section 1395w–103(a)(1) of this title, insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

(b) Application of demonstration authority

The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90–248) shall apply with respect to this part and part C in the same manner it applies with respect to parts A and B, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

(c) Coverage gap rebate for 2010

(1) In general

In the case of an individual described in subparagraphs (A) through (D) of section 1395w–114a(g)(1) of this title who as of the last day of a calendar quarter in 2010 has incurred costs for covered part D drugs so that the individual has exceeded the initial coverage limit under section 1395w–102(b)(3) of this title for 2010, the Secretary shall provide for payment from the Medicare Prescription Drug Account of $250 to the individual by not later than the 15th day of the third month following the end of such quarter.

(2) Limitation

The Secretary shall provide only 1 payment under this subsection with respect to any individual.

(d) Treatment of certain complaints for purposes of quality or performance assessment

In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–42, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2149; amended Pub. L. 111–152, title I, § 1101(a)(1), Mar. 30, 2010, 124 Stat. 1036; Pub. L. 114–198, title VII, § 704(d), July 22, 2016, 130 Stat. 750.)

REFERENCES IN TEXT

Section 402 of the Social Security Amendments of 1967, referred to in subsec. (b), is section 402 of Pub. L. 90–248, title IV, Jan. 2, 1968, 81 Stat. 930, which enacted section 1395b–1 of this title and amended section 1395*ll* of this title.

AMENDMENTS

2016—Subsec. (d). Pub. L. 114–198 added subsec. (d).
2010—Subsec. (c). Pub. L. 111–152 added subsec. (c).

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114–198 applicable to prescription drug plans (and MA–PD plans) for plan years beginning on or after Jan. 1, 2019, see section 704(g)(1) of Pub. L. 114–198, set out as a note under section 1395w–101 of this title.

§ 1395w–153. Condition for coverage of drugs under this part

(a) In general

In order for coverage to be available under this part for covered part D drugs (as defined in section 1395w–102(e) of this title) of a manufacturer, the manufacturer must—

(1) participate in the Medicare coverage gap discount program under section 1395w–114a of this title;

(2) have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and

(3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section.

(b) Effective date

Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.

(c) Authorizing coverage for drugs not covered under agreements

Subsection (a) shall not apply to the dispensing of a covered part D drug if—

(1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

(2) the Secretary determines that in the period beginning on January 1, 2011, and[1] December 31, 2011, there were extenuating circumstances.

(d) Definition of manufacturer

In this section, the term ''manufacturer'' has the meaning given such term in section 1395w–114a(g)(5) of this title.

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[1] So in original. Probably should be followed by ''ending on''.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–43, as added Pub. L. 111–148, title III, § 3301(a), Mar. 23, 2010, 124 Stat. 461; amended Pub. L. 111–152, title I, § 1101(b)(1), Mar. 30, 2010, 124 Stat. 1037.)

AMENDMENTS

2010—Subsec. (b). Pub. L. 111–152, § 1101(b)(1)(A), substituted ''January 1, 2011'' for ''July 1, 2010''.

Subsec. (c)(2). Pub. L. 111–152, § 1101(b)(1)(B), substituted ''January 1, 2011, and December 31, 2011,'' for ''July 1, 2010, and ending on December 31, 2010,''.

§ 1395w–154. Improved Medicare prescription drug plan and MA–PD plan complaint system

(a) In general

The Secretary shall develop and maintain a complaint system, that is widely known and easy to use, to collect and maintain information on MA–PD plan and prescription drug plan complaints that are received (including by telephone, letter, e-mail, or any other means) by the Secretary (including by a regional office of the Department of Health and Human Services, the Medicare Beneficiary Ombudsman, a subcontractor, a carrier, a fiscal intermediary, and a Medicare administrative contractor under section 1395kk–1 of this title) through the date on which the complaint is resolved. The system shall be able to report and initiate appropriate interventions and monitoring based on substantial complaints and to guide quality improvement.

(b) Model electronic complaint form

The Secretary shall develop a model electronic complaint form to be used for reporting plan complaints under the system. Such form shall be prominently displayed on the front page of the Medicare.gov Internet website and on the Internet website of the Medicare Beneficiary Ombudsman.

(c) Annual reports by the Secretary

The Secretary shall submit to Congress annual reports on the system. Such reports shall include an analysis of the number and types of complaints reported in the system, geographic variations in such complaints, the timeliness of agency or plan responses to such complaints, and the resolution of such complaints.

(d) Definitions

In this section:

(1) MA–PD plan

The term ''MA–PD plan'' has the meaning given such term in section 1395w–151(a)(9) of this title.

(2) Prescription drug plan

The term ''prescription drug plan'' has the meaning given such term in section 1395w–151(a)(14) of this title.

(3) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(4) System

The term ''system'' means the plan complaint system developed and maintained under subsection (a).

(Pub. L. 111–148, title III, § 3311, Mar. 23, 2010, 124 Stat. 475.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Social Security Act which comprises this chapter.

PART E—MISCELLANEOUS PROVISIONS

CODIFICATION

Pub. L. 108–173, title I, § 101(a)(1), Dec. 8, 2003, 117 Stat. 2071, redesignated part D of this subchapter as part E.

Pub. L. 105–33, title IV, § 4001, Aug. 5, 1997, 111 Stat. 275, redesignated part C of this subchapter as part D.

§ 1395x. Definitions

For purposes of this subchapter—

(a) Spell of illness

The term ''spell of illness'' with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1395i–3(a)(1) of this title or subsection (y)(1).

(b) Inpatient hospital services

The term ''inpatient hospital services'' means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional